EPA Pesticide Petition No. 5F8410

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.612, add alphabetically "Sugarcane, cane" in the table in paragraph (a) to read as follows:

§ 180.612 Topramezone; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Sugarcane, cane	0.01
* * * * *	

[FR Doc. 2017–15744 Filed 7–27–17; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2016–0284; FRL–9961–77]

Pseudomonas chlororaphis strain AFS009; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of *Pseudomonas chlororaphis* strain AFS009 in or on all food commodities when used in accordance with label directions and good agricultural practices. AFS009 Plant Protection, Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establisb a maximnm permissible level for residues of *Pseudomonas chlororaphis* strain AFS009 under FFDCA.

DATES: This reguletion is effective July 28, 2017. Objections end requests for hearings must be received on or before September 26, 2017, and must be filed in accordance with the iustructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2016–0284, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Mouday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, aud the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Robert McNally, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *BPPDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Informetion

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industriel Classification System (NAICS) codes is not intended to be exhaustive, but ratber provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal prodnctiou (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. Haw can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2016–0284 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before September 26, 2017. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed pnblicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2016–0284, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online iustructions for submitting comments. Do not snbmit electronically any information you consider to be CBI or other information wbose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.* Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available et *http://www.epa.gov/dockets.*

II. Background

In the **Federal Register** of June 22, 2016 (81 FR 40594) (FRL–9947–32), EPA issned a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 5F8410) by AFS009 Plant Protection, Inc., 104 T.W. Alexander Dr., Building 18, Research Triangle Park, NC 27709. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requiremeut of e tolerance for residues of *Pseudomonas chlororaphis* subsp. *aurantiaco* strain AFS009 in or on all food commodities. That document referenced a summary of tbe petition prepared by the petitioner AFS009 Plant Protection, Inc., which is available iu the docket via *http://www.regulations.gov.* One comment was received on the notice of filing. EPA's response to this comment is discussed in Unit III.C.

Since the time the originel notice of filing was published, the petitioner provided additional data on the identity

of tbe active ingredient to EPA. After reviewing these data, EPA now considers the correct identity of the active ingredient to be *Pseudomonas chlaroraphis* strain AFS009 and not *Pseudomonas chlororaphis* snbsp. *aurantiaca* strain AFS009. In order to give the public an opportunity to comment on this new information, EPA republished its receipt of this tolerance exemption petition filing with an updated and accurate description in the **Federal Register** of December 20, 2016 (81 FR 92758) (FRL–9956–04) and placed a revised petition from AFS009 Plant Protection, Inc. into the docket. There were no comments received in response to the republished notice of filing.

III. Final Rule

A. EPA's Sofety Determination

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is "safe." Section 408(c)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, iucluding all anticipated dietary exposures and all other exposures for whicb there is reliable information." This includes exposure through drinking water and in residential settiugs but does not include occupational exposure. Pursuant to FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the fectors set forth in FFDCA section 408(b)(2)(C), which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue iu establishing a tolerance or tolerance exemption and to "ensure thet there is a reasouable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue . . . ." Additionally, FFDCA section 408(b)(2)(D) requires tbat EPA consider "available information concerning the cumulative effects of [a particular pesticide's] . . . residues and other substances that bave e common mechanism of toxicity."

EPA evalnated the available toxicological and exposure deta on *Pseudomonas chlororaphis* strain AFS009 and cousidered its validity, completeness, and reliability, as well as the relationship of this information to humeu risk. A full expleuation of the dete upon which EPA relied and its assessments based on those data can be fonnd within the June 1, 2017, document entitled "Federal Food, Drug, and Cosmetic Act (FFDCA) Considerations for *Pseudomonas chlororaphis* strain AFS009." Tbis document, as well as other relevant information, is available in the docket for this action as described under **ADDRESSES**.

Based upon its evaluation, EPA concludes that *Pseudomonas chlororaphis* strain AFS009 is not likely to be toxic, is not pathogenic, and is not infective. Although there may be some exposure to residues when used on all food commodities in accordance with label directions and good agricultural practices, there is a lack of concern due to the lack of potential for adverse effects. EPA also determined that retention of the Food Quality Protection Act (FQPA) safety factor was not necessary as part of the qualitative assessment conducted for *Pseudomonas chlororophis* strain AFS009.

Based upon its evaluation, EPA conclndes that tbere is a reesonable certainty that no harm will result to the U.S. population, including infauts eud children, from eggregate exposure to residues of *Pseudamonas chlororaphis* strain AFS009. Therefore, an exemptiou from the requirement of a tolerance is established for residues of *Pseudamonas chlororaphis* strain AFS009 in or on all food commodities when used in accordance with label directions and good agricultural practices.

B. Analytical Enforcement Methodology

Due to the lack of toxicity, iufectivity, and pathogenicity of *Pseudamonas chlararaphis* strain AFS009, EPA has determined that there is no need for an analytical method to meesure end detect residues in or ou food.

C. Response to Comments

One comment ou the Notice of Filing was received. That comment opposed allowing residues of this pesticide on food but provided no additional information to support a conclusion that tbe substence is unsafe. EPA evaluated the available informatiou on *Pseudomonas chlararaphis* strain AFS009, including toxicity and potential exposure, and concluded, in accordence with the statutory requirements of the FFDCA, that the exemption would be safe. The commenter has provided no basis for a different conclusion.

IV. Statutory and Executive Order Reviews

This action establishes a tolerance exemption under FFDCA section 408(d) in response to a petitiou submitted to EPA. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review nnder Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Snpply, Distribution, or Use" (66 FR 28355, May 22, 2001), or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). Tbis ection does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations nuder Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populetions and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance exemption in this ection, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes. As a result, this action does not alter the relationships or distribution of power and responsibilities establisbed by Congress in the preemption provisions of FFDCA section 408(n)(4). As snch, EPA has determined that this action will not have a substantial direct effect ou States or tribal governments, on the relationship betweeu the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of goverument or between the Federal Government and Indian tribes. Thus, EPA has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999), and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000), do not apply to this actiou. Iu additiou, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Uufunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require

EPA's consideration of volnntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

V. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This actiou is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 23, 2017.

Richard P. Keigwin, Jr.,

Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Add § 180.1341 to subpart D to read as follows:

§ 180.1341 *Pseudomonas chlororaphis* etrain AFS009; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of *Pseudomonas chlororaphis* strain AFS009 in or on all food commodities when used in accordauce with label directions aud good agricultural practices.

[FR Doc. 2017–15741 Filed 7–27–17; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 424

[CMS–6059–N7]

Medicare, Medicaid, and Children's Health Insurance Programs: Announcement of the Extension of Temporary Moratoria on Enrollment of Part B Non-Emergency Ground Ambulance Suppliers and Home Health Agencies in Designated Geographic Locations

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Extension of temporary moratoria.

SUMMARY: This document announces the extension of statewide temporary moratoria on the enrollment of new Medicare Part B non-emergency ground ambulance providers and suppliers and Medicare home health agencies, subunits, and branch locations in Florida, Illinois, Michigan, Texas, Pennsylvania, and New Jersey, as applicable, to prevent and combat fraud, waste, and abuse. This extension also applies to the eurollment of new non-emergency ground ambulance suppliers and home health agencies, subunits, and branch locations in Medicaid and the Children's Health Insurance Program in those states.

DATES: Applicable July 29, 2017.

FOR FURTHER INFORMATION CONTACT: Steve Manning, (410) 786–1691.

News media representatives must contact CMS' Public Affairs Office at (202) 690–6145 or email them at *press@cms.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

A. CMS' Implementation of Temporary Enrollment Moratoria

Under the Patient Protection and Affordable Care Act (Pub. L. 111–148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) (collectively kuown as the Affordable Care Act), the Congress provided the Secretary with new tools and resources to combat fraud, waste, and abuse in Medicare, Medicaid, and the Children's Health Insurance Program (CHIP). Section 6401(a) of the Affordable Care Act added a new section 1866(j)(7) to the Social Security Act (the Act) to provide the Secretary with authority to impose a temporary moratorium ou the enrollment of uew Medicare, Medicaid or CHIP providers and suppliers, including categories of providers and suppliers, if the Secretary determines a moratorium is necessary to prevent or combat fraud, waste, or abuse under these programs. Section 6401(b) of the Affordable Care Act added specific moratorium language applicable to Medicaid at section 1902(kk)(4) of the Act, requiring States to comply with any moratorium imposed by the Secretary unless the State determines that the imposition of such moratorium would adversely impact Medicaid beneficiaries' access to care. Section 6401(c) of the Affordable Care Act amended section 2107(e)(1) of the Act to provide that all of the Medicaid provisions in sections 1902(a)(77) and 1902(kk) are also applicable to CHIP.

In the February 2, 2011 **Federal Register** (76 FR 5862), CMS published a final rule with comment period titled, "Medicare, Medicaid, and Children's Health Insurance Programs; Additional Screening Requirements, Applicatiou Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers," which implemented section 1866(j)(7) of the Act by establishing new regulations at 42 CFR 424.570. Under § 424.570(a)(2)(i) and (iv), CMS, or CMS in consultation with the Department of Health and Human Services' Office of Inspector General (HHS–OIG) or the Department of Justice (DOJ), or both, may impose a temporary moratorium on newly enrolling Medicare providers and suppliers if CMS determines that there is a significant potential for fraud, waste, or abuse with respect to a particular provider or supplier type, or particular geographic locations, or both. At § 424.570(a)(1)(ii), CMS stated that it would announce any temporary moratorium in a **Federal Register** document that includes the rationale for the imposition of such moratorium. This document fulfills that requirement.

In accordance with section 1866(j)(7)(B) of the Act, there is no judicial review uuder sections 1869 and 1878 of the Act, or otherwise, of the decision to impose a temporary enrollment moratorium. A provider or supplier may use the existing appeal procedures at 42 CFR part 498 to administratively appeal a denial of billing p.ivileges based on the imposition of a temporary moratorium; however, the scope of any such appeal is limited solely to assessing whether the temporary moratorium applies to the provider or supplier appealing the denial. Under § 424.570(c), CMS denies the enrollment application of a provider or supplier if the provider or supplier is subject to a moratorium. If the provider

Federal Food, Drug, and Cosmetic Act (FFDCA) Considerations for *Pseudomonas chlororaphis* strain AFS009

Docket ID Number: EPA-HQ-OPP-2016-0284
Date: June 1, 2017

Section 408(c)(2)(A)(i) of FFDCA allows the U.S. Environmental Protection Agency (EPA) to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is "safe." Section 408(c)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings but does not include occupational exposure. Pursuant to FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C), which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance or tolerance exemption and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue . . . ." Additionally, FFDCA section 408(b)(2)(D) requires that EPA consider "available information concerning the cumulative effects of [a particular pesticide's] . . . residues and other substances that have a common mechanism of toxicity."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, for microbial pesticides, EPA determines the pathogenicity and toxicity potential of the pesticide in tiered testing. Second, EPA examines exposure to the pesticide through food, drinking water, and other exposures that occur as a result of pesticide use in residential settings, as well as other non-occupational exposure to the substance.

I. Summary of Petitioned-for Tolerance Exemption

In the Federal Register of June 22, 2016 (81 FR 40594), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 5F8410) by AFS009 Plant Protection, Inc., 104 T.W. Alexander Dr., Building 18, Research Triangle Park, NC 27709. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009 in or on all food commodities. That document referenced a summary of the petition prepared by the petitioner AFS009 Plant Protection, Inc., which is available in Docket ID Number EPA-HQ-OPP-2016-0284 via *http://www.regulations.gov*. One general comment opposing the establishment of the exemption was received.

Since the time the original notice of filing was published, the petitioner provided additional data on the identity of the active ingredient to EPA. After reviewing these data, EPA now considers the correct identity of the active ingredient to be *Pseudomonas chlororaphis* strain AFS009 and not *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009. In order to give the public an opportunity to comment on this new information, EPA republished its receipt of this tolerance exemption petition filing with an updated and accurate description in the Federal Register of December 20, 2016 (81 FR 92758) and placed a revised petition from AFS009 Plant Protection, Inc. into the docket. No comments were received on this latter notice.

II. Toxicological Profile

Consistent with FFDCA section 408(b)(2)(D), EPA reviewed the available scientific data and other relevant information on *Pseudomonas chlororaphis* strain AFS009 and considered its validity, completeness, and reliability, as well as the relationship of this information to human risk. EPA also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The overall conclusions from all toxicological information submitted by the petitioner are briefly described below. More in-depth synopses of study results can be found in the risk assessment (Ref. 1) and other supporting science document (Ref. 2).

A. Overview of Pseudomonas chlororaphis strain AFS009

Pseudomonas chlororaphis strain AFS009 is a Gram-negative, fluorescent, Pseudomonad bacterium originally isolated from cotton plant roots in Texas. Fluorescent Pseudomonads were discovered when wheat fields resistant to root rots, including from *Pythium* and "Take-all root rot" (*Gaeumannomyces graminis*), were found to harbor these microbes on their roots while susceptible fields lacked them. Ongoing research identified certain antifungal compounds known as phenazines, namely phenazine-1-carboxylic acid (CAS No. 2538-68-3), that strongly correlated with disease control (Ref. 3). *Pseudomonas chlororaphis* strain AFS009, like other fluorescent Pseudomonads, colonizes the roots of plants and competes for niches plant-pathogenic fungi may also occupy, in the process producing various inhibitory metabolites that also affect these fungi.

Environmental fluorescent *Pseudomonas* species, including *Pseudomonas chlororaphis*, occur naturally in the environment and on food, and no foodborne disease outbreaks or toxin production from *Pseudomonas chlororaphis* in food or feed have been reported. In fact, other strains of *Pseudomonas chlororaphis* have been investigated as inhibitors of foodborne pathogens.

B. Microbial Pesticide Toxicology Data Requirements

Acute toxicity (acute oral, inhalation, and dermal toxicity) and irritation tests (acute eye and primary dermal irritation) performed with *Pseudomonas chlororaphis* strain AFS009 addressed potential routes of exposure to the active ingredient and reveal no toxicity or irritation attributed to *Pseudomonas chlororaphis* strain AFS009 (Toxicity Category IV) (Refs. 1 and 4). In the acute oral toxicity/pathogenicity study performed with *Pseudomonas chlororaphis* strain AFS009, there was no evidence of toxicity, pathogenicity, or infectivity when rats were administered 3.73×10^9 colony-forming units (CFU) per rat by oral gavage. Scientific rationale for the acute pulmonary toxicity/pathogenicity and the acute injection toxicity/pathogenicity data requirements was determined to be adequate to support waiving these two studies, based on the above findings and because the microbe grows best below 86°F (30°C) and in the presence of oxygen and is unlikely to grow or metabolize at higher temperatures[1] or with oxygen limitations.

In light of the adequacy of the toxicological data, scientific rationale, and literature (Refs. 3, 5, and 6) provided by the petitioner, EPA did not require toxicological testing at higher tiers. Based on animal testing of *Pseudomonas chlororaphis* strain AFS009, no toxicity, irritation, infectivity, pathogenicity or other adverse effects attributed to *Pseudomonas chlororaphis* strain AFS009 are expected.

[1] Normal human body temperature ranges between 97.7°F (36.5°C) and 99.5°F (37.5°C). Thus, if *Pseudomonas chlororaphis* strain AFS009 were introduced into the human body, it likely would not cause infection or be pathogenic.

1. *Acute Oral Toxicity/Pathogenicity – Rat (Harmonized Guideline 885.3050; Master Record Identification Number (MRID No.) 495680-02).* An acceptable acute oral toxicity and pathogenicity study demonstrated that *Pseudomonas chlororaphis* strain AFS009 is not toxic, infective, or pathogenic by oral gavage of 3.73 x 10^9 CFU/rat. The test substance cleared from most tissues by day 14. While there was low detection in mesenteric lymph nodes of some animals on days 14 and 21, the 21-day study showed a distinct pattern of clearance from the gastrointestinal tract with no signs of infectivity, pathogenicity, or toxicity. (Ref. 1).

2. *Acute Oral Toxicity – Rat (Harmonized Guideline 870.1100; MRID No. 495680-03).* An acceptable acute oral toxicity study demonstrated *Pseudomonas chlororaphis* strain AFS009 is not toxic to female rats when dosed at 5,000 mg/Kg body weight. The oral no observed adverse effect level (NOAEL) for female rats was greater than 5,000 mg/Kg body weight (Toxicity Category IV). (Ref. 1).

3. *Acute Inhalation Toxicity – Rat (Harmonized Guideline 870.1300; MRID No. 495680-05).* In an acute inhalation toxicity study, groups of young adult Sprague-Dawley rats (5/sex/group) were exposed nose-only to Howler Technical containing 100% *Pseudomonas chlororaphis* strain AFS009 aerosolized for 4 hours at a concentration of 5.04 mg/L. The animals were observed for 14 days. All animals survived the study. Labored breathing was seen in all animals at one hour after the exposure period with recovery by day 1 in most animals. Labored breathing persisted in only one male after one hour and lasted until day 6. One animal exhibited hypoactivity for one hour post removal. On days 7-14, all animals were reported as active and healthy. All animals lost weight from the exposure but gained it back or surpassed their starting weight by days 3-7. At day 14, all animals showed normal weight gain. No observed abnormalities were noted at necropsy. The inhalation median lethal concentration (LC_{50}), which is a statistically derived concentration that can be expected to cause death in 50% of test animals, for both male and female rats was greater than 5.04 mg/L (Toxicity Category IV). (Refs. 1 and 2).

It is generally observed that labored breathing, hunched posture, and hypoactivity are signs of receiving a dose by the inhalation route, especially if the dosing rate is at or near the limit dose (2-5 mg/L). There is also consideration of whether the clinical signs are reversible as this indicates recovery from any dosing effect. It is noted that mortality and morbidity are the sole endpoints for the proper assignment of toxicity category for this test. The most credible explanation for the labored breathing and hypoactivity seen in this acute inhalation toxicity test was a response to high concentrations of dosing material. These clinical signs are not considered indicative of a systemic toxicity due to the bacterial agent but due to a high concentration of test material in the test chamber (Ref. 2.)

4. *Acute Pulmonary Toxicity/Pathogenicity and Acute Injection Toxicity/Pathogenicity (Harmonized Guidelines 885.3150 and 885.3200; MRID No. 495680-16).* No acute pulmonary toxicity/pathogenicity or acute injection toxicity/pathogenicity studies were submitted; instead, a scientific rationale was submitted requesting waiver of these data requirements. The Agency determined that these data were not necessary and waived the requirements for these data based on the following: (1) the lack of evidence of adverse effects in the acute oral toxicity/pathogenicity study and the acute oral toxicity study; (2) the transience of the impacts in the acute inhalation toxicity study; and (3) the knowledge that the microbe grows best below 86°F (30°C) and in the presence of oxygen. Based on this information, EPA was able to assess the potential of *Pseudomonas chlororaphis* strain AFS009 to cause infection or pathogenicity by the pulmonary or injection routes of exposure. The temperature (below 30°C) and oxygen growth limitations[2] of this microbe are not expected to lead to infection during an intravenous exposure study. There was adequate evidence from an acute oral toxicity/pathogenicity study that the microbe was not infectious. Natural exposures

[2] *Pseudomonas chlororaphis* is an aerobe and requires available oxygen.

through food to Gram-negative microbes in general are already widespread and harmless if the microbes are not pathogens. *Pseudomonas chlororaphis* strain AFS009 is not identified as a mammalian pathogen in the scientific literature, and this status is supported by the acute oral toxicity/pathogenicity test results and a literature review. The results of the acceptable oral toxicity/pathogenicity study with a demonstrated pattern of clearance address the injection route of exposure and support waiving the acute injection toxicity/pathogenicity study. The results of the acute inhalation toxicity study with a 4-hour exposure and no mortalities address the inhalation endpoint and support waiving the acute pulmonary toxicity/pathogenicity study. (Ref. 1).

5. *Acute Dermal Toxicity – Rat (Harmonized Guideline 870.1200; MRID No. 495680-04).* An acceptable acute dermal toxicity study demonstrated that *Pseudomonas chlororaphis* strain AFS009 was not toxic to male and female rats when dosed at 5,000 mg/Kg of body weight for 24 hours. The dermal NOAEL for male and female rats was greater than 5,000 mg/Kg body weight (Toxicity Category IV). (Ref. 1).

6. *Acute Eye Irritation – Rabbit (Harmonized Guideline 870.2400; MRID No. 495680-06).* An acceptable acute eye irritation study demonstrated that *Pseudomonas chlororaphis* strain AFS009 was not irritating to the eye (Toxicity Category IV). (Ref. 1).

7. *Primary Dermal Irritation – Rabbit (Harmonized Guideline 870.2500; MRID No. 495680-07).* An acceptable primary dermal irritation study demonstrated that *Pseudomonas chlororaphis* strain AFS009 was not dermally irritating (Toxicity Category IV). (Ref. 1).

Based on the lack of toxicity, infectivity, or pathogenicity in any of the available studies, EPA has not identified any toxicological points of departure. Consequently, EPA's aggregate risk assessment of the *Pseudomonas chlororaphis* strain AFS009 is qualitative, rather than quantitative, in nature.

III. Aggregate Exposure

In examining aggregate exposure, FFDCA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

Food Exposure: *Pseudomonas chlororaphis* is naturally found in agricultural settings (i.e., in water, in soils and on plants), and use of *Pseudomonas chlororaphis* strain AFS009 as a pesticide on food is expected to result in residues in or on food. When consumers wash their produce, it is anticipated that levels of *Pseudomonas chlororaphis* strain AFS009 and its associated metabolites may be reduced.

Drinking Water Exposure: Since *Pseudomonas chlororaphis* is naturally present in soils and on plants, exposure to *Pseudomonas chlororaphis* from surface water and possibly ground water can be expected. Moreover, use of *Pseudomonas chlororaphis* strain AFS009 as a pesticide on food is expected to result in residues in or on drinking water. Water treatment processes should remove any *Pseudomonas chlororaphis* strain AFS009 present. Should this microbial pesticide be present, no adverse effects are expected from exposure to *Pseudomonas chlororaphis* strain AFS009 through drinking water, based on the results of the toxicological studies.

Other Non-Occupational Exposure: Since the *Pseudomonas chlororaphis* strain AFS009 end-use products allow for applications in residential settings, including to bedding plants, annuals and perennials, home gardens, and ornamental trees and shrubs, exposure to the bacterium from its pesticide use would be likely.

Pseudomonads, however, are already present in soil and on plant roots, and exposures to *Pseudomonas chlororaphis* strain AFS009 from pesticidal applications do not present a risk concern, particularly in light of available data that demonstrate it is not toxic or irritating and is not likely to be infective or pathogenic:

1. *Dermal exposure. Pseudomonas chlororaphis* strain AFS009 was shown to be non-toxic and is not irritating to the skin (acute dermal toxicity and primary dermal irritation data).

2. *Inhalation exposure. Pseudomonas chlororaphis* strain AFS009 was shown to be non-toxic and is not likely to be pathogenic or infective. Initial high doses to the lungs caused transitory effects that cleared within all animals except one by 24 hours. These transitory clinical signs are not considered indicative of a systemic toxicity due to the bacterial agent but due to a high concentration of test material in the test chamber (Ref. 2). Inhalation of large quantities of *Pseudomonas chlororaphis* strain AFS009 is not expected for homeowner applications because a concentrated product is not used for purposes other than manufacture and repeated exposure of high doses of concentrated product in home and garden sites is not anticipated.

IV. Cumulative Effects from Substances with a Common Mechanism of Toxicity

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, EPA consider "available information concerning the cumulative effects of [a particular pesticide's] . . . residues and other substances that have a common mechanism of toxicity."

Pseudomonas chlororaphis strain AFS009 is not toxic and does not have a common mechanism of toxicity with other substances. Consequently, FFDCA section 408(b)(2)(D)(v) does not apply.

V. Determination of Safety for the U.S. Population, Infants and Children

A. U.S. Population

For all of the reasons discussed previously, EPA concludes that there is reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of *Pseudomonas chlororaphis* strain AFS009. This includes all anticipated dietary exposures and all other exposures for which there is reliable information.

B. Infants and Children

FFDCA section 408(b)(2)(C) provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure, unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor. In applying this provision, EPA either retains the default value of 10X or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

No endpoints were identified based on the available data for *Pseudomonas chlororaphis* strain AFS009, and differential effects to infants and children are not expected. Pseudomonads, such as *Pseudomonas chlororaphis* strain AFS009, are already very commonly present on a wide range of foods, including those consumed raw or with minimal processing. Because there are no threshold levels of concern to infants and children from *Pseudomonas chlororaphis* strain AFS009, EPA concludes that no additional margin of

safety is necessary to protect infants and children.

VI. Conclusion

EPA concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of *Pseudomonas chlororaphis* strain AFS009. Therefore, EPA is establishing an exemption from the requirement of a tolerance for residues of *Pseudomonas chlororaphis* strain AFS009 in or on all food commodities when used in accordance with label directions and good agricultural practices.

VII. References

1. U.S. EPA. 2016. Howler products containing *Pseudomonas chlororaphis* strain AFS009. Memorandum from J.V. Gagliardi, Ph.D. through J.L. Kough, Ph.D. to S. Cerrelli dated November 15, 2016 (available as a "Supporting Document" within Docket ID Number EPA-HQ-OPP-2016-0251 at *http://www.regulations.gov*).

2. U.S. EPA. 2017. Comments on Acute Inhalation Toxicity Study (870.1300) for Microbial Pesticide Technical *Pseudomonas chlororaphis* AFS 009. Memorandum from J.L. Kough, Ph.D. and M. Perry to M. Mendelsohn dated May 9, 2017 (available as a "Supporting Document" within Docket ID Number EPA-HQ-OPP-2016-0251 at *http://www.regulations.gov*).

3. Khan, A., J.C. Sutton and B. Grodzinski. 2003. Effects of *Pseudomonas chlororaphis* on *Pythium aphanidermatum* and Root Rot in Peppers Grown in Small-scale Hydroponic Troughs. Biocontrol Science and Technology 13(6):615-630.

4. U.S. EPA. 2014. Chapter 7 of the Label Review Manual (Precautionary Statements) (Revised July 2014). Available from *https://www.epa.gov/sites/production/files/2015-03/documents/chap-07-jul-2014.pdf*.

5. Shen, X., M. Chen, H. Hu, W. Wang, H. Peng, P. Xu and X. Zhang. 2012. Genome Sequence of *Pseudomonas chlororaphis* GP72, a Root-Colonizing Biocontrol Strain. Journal of Bacteriology 194(5):1269-1270.

6. Tombolini, R., D.J. van der Gaag, B. Gerhardson and J.K. Jansson. 1999. Colonization Pattern of the Biocontrol Strain *Pseudomonas chlororaphis* MA 342 on Barley Seeds Visualized by Using Green Fluorescent Protein. Applied and Environmental Microbiology 65(8):3674-3680.

Federal Food, Drug, and Cosmetic Act (FFDCA) Considerations for *Pseudomonas chlororaphis* strain AFS009

Docket ID Number: EPA-HQ-OPP-2016-0284
Date: June 1, 2017

Section 408(c)(2)(A)(i) of FFDCA allows the U.S. Environmental Protection Agency (EPA) to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is "safe." Section 408(c)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings but does not include occupational exposure. Pursuant to FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C), which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance or tolerance exemption and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue . . . ." Additionally, FFDCA section 408(b)(2)(D) requires that EPA consider "available information concerning the cumulative effects of [a particular pesticide's] . . . residues and other substances that have a common mechanism of toxicity."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, for microbial pesticides, EPA determines the pathogenicity and toxicity potential of the pesticide in tiered testing. Second, EPA examines exposure to the pesticide through food, drinking water, and other exposures that occur as a result of pesticide use in residential settings, as well as other non-occupational exposure to the substance.

I. Summary of Petitioned-for Tolerance Exemption

In the Federal Register of June 22, 2016 (81 FR 40594), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 5F8410) by AFS009 Plant Protection, Inc., 104 T.W. Alexander Dr., Building 18, Research Triangle Park, NC 27709. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009 in or on all food commodities. That document referenced a summary of the petition prepared by the petitioner AFS009 Plant Protection, Inc., which is available in Docket ID Number EPA-HQ-OPP-2016-0284 via *http://www.regulations.gov*. One general comment opposing the establishment of the exemption was received.

Since the time the original notice of filing was published, the petitioner provided additional data on the identity of the active ingredient to EPA. After reviewing these data, EPA now considers the correct identity of the active ingredient to be *Pseudomonas chlororaphis* strain AFS009 and not *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009. In order to give the public an opportunity to comment on this new information, EPA republished its receipt of this tolerance exemption petition filing with an updated and accurate description in the Federal Register of December 20, 2016 (81 FR 92758) and placed a revised petition from AFS009 Plant Protection, Inc. into the docket. No comments were received on this latter notice.

II. Toxicological Profile

Consistent with FFDCA section 408(b)(2)(D), EPA reviewed the available scientific data and other relevant information on *Pseudomonas chlororaphis* strain AFS009 and considered its validity, completeness, and reliability, as well as the relationship of this information to human risk. EPA also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The overall conclusions from all toxicological information submitted by the petitioner are briefly described below. More in-depth synopses of study results can be found in the risk assessment (Ref. 1) and other supporting science document (Ref. 2).

A. Overview of Pseudomonas chlororaphis strain AFS009

Pseudomonas chlororaphis strain AFS009 is a Gram-negative, fluorescent, Pseudomonad bacterium originally isolated from cotton plant roots in Texas. Fluorescent Pseudomonads were discovered when wheat fields resistant to root rots, including from *Pythium* and "Take-all root rot" (*Gaeumannomyces graminis*), were found to harbor these microbes on their roots while susceptible fields lacked them. Ongoing research identified certain antifungal compounds known as phenazines, namely phenazine-1-carboxylic acid (CAS No. 2538-68-3), that strongly correlated with disease control (Ref. 3). *Pseudomonas chlororaphis* strain AFS009, like other fluorescent Pseudomonads, colonizes the roots of plants and competes for niches plant-pathogenic fungi may also occupy, in the process producing various inhibitory metabolites that also affect these fungi.

Environmental fluorescent *Pseudomonas* species, including *Pseudomonas chlororaphis*, occur naturally in the environment and on food, and no foodborne disease outbreaks or toxin production from *Pseudomonas chlororaphis* in food or feed have been reported. In fact, other strains of *Pseudomonas chlororaphis* have been investigated as inhibitors of foodborne pathogens.

B. Microbial Pesticide Toxicology Data Requirements

Acute toxicity (acute oral, inhalation, and dermal toxicity) and irritation tests (acute eye and primary dermal irritation) performed with *Pseudomonas chlororaphis* strain AFS009 addressed potential routes of exposure to the active ingredient and reveal no toxicity or irritation attributed to *Pseudomonas chlororaphis* strain AFS009 (Toxicity Category IV) (Refs. 1 and 4). In the acute oral toxicity/pathogenicity study performed with *Pseudomonas chlororaphis* strain AFS009, there was no evidence of toxicity, pathogenicity, or infectivity when rats were administered 3.73×10^9 colony-forming units (CFU) per rat by oral gavage. Scientific rationale for the acute pulmonary toxicity/pathogenicity and the acute injection toxicity/pathogenicity data requirements was determined to be adequate to support waiving these two studies, based on the above findings and because the microbe grows best below 86°F (30°C) and in the presence of oxygen and is unlikely to grow or metabolize at higher temperatures[1] or with oxygen limitations.

In light of the adequacy of the toxicological data, scientific rationale, and literature (Refs. 3, 5, and 6) provided by the petitioner, EPA did not require toxicological testing at higher tiers. Based on animal testing of *Pseudomonas chlororaphis* strain AFS009, no toxicity, irritation, infectivity, pathogenicity or other adverse effects attributed to *Pseudomonas chlororaphis* strain AFS009 are expected.

[1] Normal human body temperature ranges between 97.7°F (36.5°C) and 99.5°F (37.5°C). Thus, if *Pseudomonas chlororaphis* strain AFS009 were introduced into the human body, it likely would not cause infection or be pathogenic.

1. *Acute Oral Toxicity/Pathogenicity – Rat (Harmonized Guideline 885.3050; Master Record Identification Number (MRID No.) 495680-02).* An acceptable acute oral toxicity and pathogenicity study demonstrated that *Pseudomonas chlororaphis* strain AFS009 is not toxic, infective, or pathogenic by oral gavage of 3.73 x 10^9 CFU/rat. The test substance cleared from most tissues by day 14. While there was low detection in mesenteric lymph nodes of some animals on days 14 and 21, the 21-day study showed a distinct pattern of clearance from the gastrointestinal tract with no signs of infectivity, pathogenicity, or toxicity. (Ref. 1).

2. *Acute Oral Toxicity – Rat (Harmonized Guideline 870.1100; MRID No. 495680-03).* An acceptable acute oral toxicity study demonstrated *Pseudomonas chlororaphis* strain AFS009 is not toxic to female rats when dosed at 5,000 mg/Kg body weight. The oral no observed adverse effect level (NOAEL) for female rats was greater than 5,000 mg/Kg body weight (Toxicity Category IV). (Ref. 1).

3. *Acute Inhalation Toxicity – Rat (Harmonized Guideline 870.1300; MRID No. 495680-05).* In an acute inhalation toxicity study, groups of young adult Sprague-Dawley rats (5/sex/group) were exposed nose-only to Howler Technical containing 100% *Pseudomonas chlororaphis* strain AFS009 aerosolized for 4 hours at a concentration of 5.04 mg/L. The animals were observed for 14 days. All animals survived the study. Labored breathing was seen in all animals at one hour after the exposure period with recovery by day 1 in most animals. Labored breathing persisted in only one male after one hour and lasted until day 6. One animal exhibited hypoactivity for one hour post removal. On days 7-14, all animals were reported as active and healthy. All animals lost weight from the exposure but gained it back or surpassed their starting weight by days 3-7. At day 14, all animals showed normal weight gain. No observed abnormalities were noted at necropsy. The inhalation median lethal concentration (LC_{50}), which is a statistically derived concentration that can be expected to cause death in 50% of test animals, for both male and female rats was greater than 5.04 mg/L (Toxicity Category IV). (Refs. 1 and 2).

It is generally observed that labored breathing, hunched posture, and hypoactivity are signs of receiving a dose by the inhalation route, especially if the dosing rate is at or near the limit dose (2-5 mg/L). There is also consideration of whether the clinical signs are reversible as this indicates recovery from any dosing effect. It is noted that mortality and morbidity are the sole endpoints for the proper assignment of toxicity category for this test. The most credible explanation for the labored breathing and hypoactivity seen in this acute inhalation toxicity test was a response to high concentrations of dosing material. These clinical signs are not considered indicative of a systemic toxicity due to the bacterial agent but due to a high concentration of test material in the test chamber (Ref. 2.)

4. *Acute Pulmonary Toxicity/Pathogenicity and Acute Injection Toxicity/Pathogenicity (Harmonized Guidelines 885.3150 and 885.3200; MRID No. 495680-16).* No acute pulmonary toxicity/pathogenicity or acute injection toxicity/pathogenicity studies were submitted; instead, a scientific rationale was submitted requesting waiver of these data requirements. The Agency determined that these data were not necessary and waived the requirements for these data based on the following: (1) the lack of evidence of adverse effects in the acute oral toxicity/pathogenicity study and the acute oral toxicity study; (2) the transience of the impacts in the acute inhalation toxicity study; and (3) the knowledge that the microbe grows best below 86°F (30°C) and in the presence of oxygen. Based on this information, EPA was able to assess the potential of *Pseudomonas chlororaphis* strain AFS009 to cause infection or pathogenicity by the pulmonary or injection routes of exposure. The temperature (below 30°C) and oxygen growth limitations[2] of this microbe are not expected to lead to infection during an intravenous exposure study. There was adequate evidence from an acute oral toxicity/pathogenicity study that the microbe was not infectious. Natural exposures

[2] *Pseudomonas chlororaphis* is an aerobe and requires available oxygen.

through food to Gram-negative microbes in general are already widespread and harmless if the microbes are not pathogens. *Pseudomonas chlororaphis* strain AFS009 is not identified as a mammalian pathogen in the scientific literature, and this status is supported by the acute oral toxicity/pathogenicity test results and a literature review. The results of the acceptable oral toxicity/pathogenicity study with a demonstrated pattern of clearance address the injection route of exposure and support waiving the acute injection toxicity/pathogenicity study. The results of the acute inhalation toxicity study with a 4-hour exposure and no mortalities address the inhalation endpoint and support waiving the acute pulmonary toxicity/pathogenicity study. (Ref. 1).

5. *Acute Dermal Toxicity – Rat (Harmonized Guideline 870.1200; MRID No. 495680-04).* An acceptable acute dermal toxicity study demonstrated that *Pseudomonas chlororaphis* strain AFS009 was not toxic to male and female rats when dosed at 5,000 mg/Kg of body weight for 24 hours. The dermal NOAEL for male and female rats was greater than 5,000 mg/Kg body weight (Toxicity Category IV). (Ref. 1).

6. *Acute Eye Irritation – Rabbit (Harmonized Guideline 870.2400; MRID No. 495680-06).* An acceptable acute eye irritation study demonstrated that *Pseudomonas chlororaphis* strain AFS009 was not irritating to the eye (Toxicity Category IV). (Ref. 1).

7. *Primary Dermal Irritation – Rabbit (Harmonized Guideline 870.2500; MRID No. 495680-07).* An acceptable primary dermal irritation study demonstrated that *Pseudomonas chlororaphis* strain AFS009 was not dermally irritating (Toxicity Category IV). (Ref. 1).

Based on the lack of toxicity, infectivity, or pathogenicity in any of the available studies, EPA has not identified any toxicological points of departure. Consequently, EPA's aggregate risk assessment of the *Pseudomonas chlororaphis* strain AFS009 is qualitative, rather than quantitative, in nature.

III. Aggregate Exposure

In examining aggregate exposure, FFDCA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

Food Exposure: *Pseudomonas chlororaphis* is naturally found in agricultural settings (i.e., in water, in soils and on plants), and use of *Pseudomonas chlororaphis* strain AFS009 as a pesticide on food is expected to result in residues in or on food. When consumers wash their produce, it is anticipated that levels of *Pseudomonas chlororaphis* strain AFS009 and its associated metabolites may be reduced.

Drinking Water Exposure: Since *Pseudomonas chlororaphis* is naturally present in soils and on plants, exposure to *Pseudomonas chlororaphis* from surface water and possibly ground water can be expected. Moreover, use of *Pseudomonas chlororaphis* strain AFS009 as a pesticide on food is expected to result in residues in or on drinking water. Water treatment processes should remove any *Pseudomonas chlororaphis* strain AFS009 present. Should this microbial pesticide be present, no adverse effects are expected from exposure to *Pseudomonas chlororaphis* strain AFS009 through drinking water, based on the results of the toxicological studies.

Other Non-Occupational Exposure: Since the *Pseudomonas chlororaphis* strain AFS009 end-use products allow for applications in residential settings, including to bedding plants, annuals and perennials, home gardens, and ornamental trees and shrubs, exposure to the bacterium from its pesticide use would be likely.

Pseudomonads, however, are already present in soil and on plant roots, and exposures to *Pseudomonas chlororaphis* strain AFS009 from pesticidal applications do not present a risk concern, particularly in light of available data that demonstrate it is not toxic or irritating and is not likely to be infective or pathogenic:

1. *Dermal exposure. Pseudomonas chlororaphis* strain AFS009 was shown to be non-toxic and is not irritating to the skin (acute dermal toxicity and primary dermal irritation data).

2. *Inhalation exposure. Pseudomonas chlororaphis* strain AFS009 was shown to be non-toxic and is not likely to be pathogenic or infective. Initial high doses to the lungs caused transitory effects that cleared within all animals except one by 24 hours. These transitory clinical signs are not considered indicative of a systemic toxicity due to the bacterial agent but due to a high concentration of test material in the test chamber (Ref. 2). Inhalation of large quantities of *Pseudomonas chlororaphis* strain AFS009 is not expected for homeowner applications because a concentrated product is not used for purposes other than manufacture and repeated exposure of high doses of concentrated product in home and garden sites is not anticipated.

IV. Cumulative Effects from Substances with a Common Mechanism of Toxicity

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, EPA consider "available information concerning the cumulative effects of [a particular pesticide's] . . . residues and other substances that have a common mechanism of toxicity."

Pseudomonas chlororaphis strain AFS009 is not toxic and does not have a common mechanism of toxicity with other substances. Consequently, FFDCA section 408(b)(2)(D)(v) does not apply.

V. Determination of Safety for the U.S. Population, Infants and Children

A. U.S. Population

For all of the reasons discussed previously, EPA concludes that there is reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of *Pseudomonas chlororaphis* strain AFS009. This includes all anticipated dietary exposures and all other exposures for which there is reliable information.

B. Infants and Children

FFDCA section 408(b)(2)(C) provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure, unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor. In applying this provision, EPA either retains the default value of 10X or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

No endpoints were identified based on the available data for *Pseudomonas chlororaphis* strain AFS009, and differential effects to infants and children are not expected. Pseudomonads, such as *Pseudomonas chlororaphis* strain AFS009, are already very commonly present on a wide range of foods, including those consumed raw or with minimal processing. Because there are no threshold levels of concern to infants and children from *Pseudomonas chlororaphis* strain AFS009, EPA concludes that no additional margin of

safety is necessary to protect infants and children.

VI. Conclusion

EPA concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of *Pseudomonas chlororaphis* strain AFS009. Therefore, EPA is establishing an exemption from the requirement of a tolerance for residues of *Pseudomonas chlororaphis* strain AFS009 in or on all food commodities when used in accordance with label directions and good agricultural practices.

VII. References

1. U.S. EPA. 2016. Howler products containing *Pseudomonas chlororaphis* strain AFS009. Memorandum from J.V. Gagliardi, Ph.D. through J.L. Kough, Ph.D. to S. Cerrelli dated November 15, 2016 (available as a "Supporting Document" within Docket ID Number EPA-HQ-OPP-2016-0251 at *http://www.regulations.gov*).

2. U.S. EPA. 2017. Comments on Acute Inhalation Toxicity Study (870.1300) for Microbial Pesticide Technical *Pseudomonas chlororaphis* AFS 009. Memorandum from J.L. Kough, Ph.D. and M. Perry to M. Mendelsohn dated May 9, 2017 (available as a "Supporting Document" within Docket ID Number EPA-HQ-OPP-2016-0251 at *http://www.regulations.gov*).

3. Khan, A., J.C. Sutton and B. Grodzinski. 2003. Effects of *Pseudomonas chlororaphis* on *Pythium aphanidermatum* and Root Rot in Peppers Grown in Small-scale Hydroponic Troughs. Biocontrol Science and Technology 13(6):615-630.

4. U.S. EPA. 2014. Chapter 7 of the Label Review Manual (Precautionary Statements) (Revised July 2014). Available from *https://www.epa.gov/sites/production/files/2015-03/documents/chap-07-jul-2014.pdf*.

5. Shen, X., M. Chen, H. Hu, W. Wang, H. Peng, P. Xu and X. Zhang. 2012. Genome Sequence of *Pseudomonas chlororaphis* GP72, a Root-Colonizing Biocontrol Strain. Journal of Bacteriology 194(5):1269-1270.

6. Tombolini, R., D.J. van der Gaag, B. Gerhardson and J.K. Jansson. 1999. Colonization Pattern of the Biocontrol Strain *Pseudomonas chlororaphis* MA 342 on Barley Seeds Visualized by Using Green Fluorescent Protein. Applied and Environmental Microbiology 65(8):3674-3680.

Cerrelli, Susanne

From: Richard Keigwin <Keigwin.Richard@epamail.epa.gov> on behalf of Workflow Messenger <Workflow_Messenger@epamail.epa.gov>
Sent: Wednesday, June 21, 2017 3:39 PM
To: Keigwin, Richard; Cerrelli, Susanne
Subject: Recommendation of Division Directors Negotiated Due Dates has been completed by Richard Keigwin.

Recommendation of Division Directors Negotiated Due Dates has been completed by Richard Keigwin.

Author: Susanne Cerrelli
Chemical: Pseudomonas chlororaphis strain AFS009
Form Date: 06/20/2017
Decision #: 510007

Registration #:

Petition #: 5F8410

Original PRIA Due Date: 03/23/2017
Previous Negotiated Due Dates: 05/05/2017, 06/21/2017, ,
Proposed New PRIA Due Date: 08/16/2017

Click on this link to access this form:
https://webforms.epa.gov/webforms/webformsadmin.nsf/formOpen?OpenAgent&UNID=CC3470D408EE4A498525814500500964&USERDB=webforms/webformsapp.nsf

Recommendation of Division Directors
Negotiated Due Dates

Decision #: 510007	Registration #:	Petition #: 5F8410

☐ *See page 2 for additional registration entries*

Chemical Name: Pseudomonas chlororaphis strain AFS009

Fee Category: B590 — **PRIA Decision Time Frame:** 17 months

Submitted by: Susanne Cerrelli — **Branch:** OCSPP/OPP/BPPD — **Date:** 06/20/2017

Company: AFS009 Plant Protection, Inc.

Original PRIA Due Date: 03/23/2017 — **Proposed New PRIA Due Date:** 08/16/2017

Previous Negotiated Due Dates: 05/05/2017 06/21/2017

Is the "Fix" in-house? ☐ Yes ☐ No ☑ n/a — **If not, date "Fix" expected:**

Negotiated Due Date Reason:

Additional Data Required	☐ Product Chemistry	☐ Toxicology	☐ Acute Tox	☐ Environmental	
	☐ Efficacy	☐ Ecological	☐ Residue	☐ Other	
Data Deficiencies	☐ Product Chemistry	☐ Acute Tox	☐ Efficacy	☐ Residue	☐ Toxicology
	☐ Environmental	☐ Ecological	☐ Labeling	☐ Other	☐ Not Submitted
Late Risk Assessment	☐ Human Health	☐ Ecological			
Interim Consideration	☐ Agency Initiated	☐ Registrant Initiated			

☐ CSF	☐ Public Process	☐ Risk Issues Environmental	☐ Risk Issues Human Health
☐ Impurities Review	☐ Label	☑ Administrative-FR Notice	☑ Other – Comment Field

Summary of Deficiency Type(s): ☐ Not Submitted (N) ☐ Deficiencies (D)

Product Chemistry: ☐ **Acute Tox:** ☐ **Efficacy:** ☐ **Labeling:** ☐ **Ecological Data:** ☐ **Other (describe):** ☐

Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates):

On 06/15/2017 by phone call & email, EPA contacted the agent and proposed an extension of the PRIA due date to 08/16/2017 because the tolerance exemption associated with this action was still be processed. On 6/20/17, the agent submitted email requesting the PRIA date be extended to 08/16/2017. See the "Comment(s)" section on page 2 for additional details.

"75 Day" Letter sent? ☐ **Yes, Date sent** ☑ **No and reason for none?** *Add comments on page 2*

Rationale for Proposed Due Date:

Registrant notified that this is the last negotiation? ☐ **Yes** ☑ **Not Applicable**

Approve: ☑ **Disapprove:** ☐

If disapproved, action to be taken:

OD or DOD Signature: *CN=Richard Keigwin/OU=DC/O=USEPA/C=US* **Date:** *06/21/2017*

Decision #:	Registration #:	Petition #:

Issue(s) (describe in detail):

Because of internal disagreement between science reviewers on some of the text related to the acute inhalation toxicity test done with the active ingredient (i.e., clinical signs vs. signs of toxicity) in the tolerance exemption documents, BPPD was working on addressing additional comments from the Office of General Counsel. (*Note: The acute inhalation toxicity test has been classified as Toxicity Category IV, and the sign at issue was irregular respiration noted in the animals for 1-6 hours upon their removal from the test chamber; no mortalities were reported.) BPPD has resolved this issue by including considerations of the secondary reviewer and follow-up comments from the primary reviewer in the public participation docket. The tolerance exemption documents are finalized, and they are in the process of being routed to the Office Director for signature and sent to the Regulatory Coordination Staff for further processing. Part of this processing involves review by the Office of Policy (OP), and the review time seems to have varied anywhere from a few weeks to a few months. This action cannot be approved until the tolerance exemption final rule clears OP and publishes in the Federal Register.

Comment(s):

Continued from "Interactions with Company" section on page 1 -

Here is history of the prior two renegotiation date requests:
In an 04/06/2017 email, EPA contacted the agent and proposed an extension of the PRIA due date to 05/26/2017 because this tolerance exemption action was still be processed. Hearing nothing further after this correspondence, EPA sent a follow-up email to the agent on 04/10/2017. The agent responded the same day and said that he would call EPA the next day to discuss further. On 04/11/2017, EPA and the agent had a phone conversation, during which EPA explained the remaining tasks that needed to be completed for this action and the agent expressed concern over an extension of approximately 6 weeks because of his client potentially missing the growing season. The same day, the agent sent an email to EPA, agreeing to a new PRIA due date of 05/08/2017. On May 4, 2017 the RAL notified the Agent that the tolerance exemption and the related registration would not be issued by May 8, 2017. On May 4, 2017, affer sending a rebuttal to the RAL concerning a suggested July 5, 2017 PRIA date, a request for June 21, 2017 PRIA date was emailed by the Agent.

Reason for not doing a 75-day deficiency letter -
At this time, there are no deficiencies that the applicant needs to address; thus, a 75-day deficieny letter is not warranted.

"Other - Comment Field" checked on page 1 -
See "Issue(s)" section above.

Audit Trail for

Recommendation of Division Directors Negotiated Due Dates

PDF Name: PRIAv5.pdf
Form Number: PRIA
Document Identifier: PRIA-17171103412-SC

SUBMITTED on 06/20/2017 at 10:50:10 AM by CN=Susanne Cerrelli/OU=DC/O=USEPA/C=US

APPROVED on 06/20/2017 at 04:55:52 PM by CN=Mike Mendelsohn/OU=DC/O=USEPA/C=US

APPROVED on 06/21/2017 at 09:04:55 AM by CN=John Leahy/OU=DC/O=USEPA/C=US

APPROVED AND COMPLETED on 06/21/2017 at 03:39:12 PM by CN=Richard Keigwin/OU=DC/O=USEPA/C=US

Cerrelli, Susanne

From: Jacob Moore <JMoore@tsgusa.com>
Sent: Monday, June 19, 2017 4:08 PM
To: Cerrelli, Susanne
Cc: Kausch, Jeannine
Subject: RE: EPA File Symbol 91197-G , petition 5F8410 and the PRIA due date

Follow Up Flag: Follow up
Flag Status: Flagged

Dear Susanne,

Thank you again for the explanatory phone call/email. We accept the revised PRIA date of August 16, 2017.

Best,

-Jacob

Jacob S. Moore | Regulatory Consultant
Technology Sciences Group Inc. (TSG)
712 Fifth Street, Suite A | Davis, CA 95616
Tel: 530-601-5064 | Fax: 530-757-1299 | jmoore@TSGUSA.com | skype: jacob_s_moore
www.TSGUSA.com

From: Cerrelli, Susanne [mailto:Cerrelli.Susanne@epa.gov]
Sent: Thursday, June 15, 2017 1:39 PM
To: Jacob Moore <JMoore@tsgusa.com>
Cc: Kausch, Jeannine <Kausch.Jeannine@epa.gov>
Subject: EPA File Symbol 91197-G , petition 5F8410 and the PRIA due date

Dear Mr. Jacob Moore-
As discussed a few minutes ago over the telephone, it does not appear that BPPD will be able to meet the current June 21, 2017 PRIA date. The tolerance exemption and the supporting document will need to be approved at several levels still. Approval is needed by the Acting Administrator of OPP, RCS, and the Office of Policy before the tolerance exemption can be published and the registration issued. We suggest that August 16, 2017 would be an appropriate PRIA date for EPA File Symbol 91197-G, petition 5F8410. Please let me know if you have any questions.

Regards,

Susanne Cerrelli
Regulatory Action Leader
Biopesticides Pollution Prevention Division

703-308-8077

Cerrelli, Susanne

From: Cerrelli, Susanne
Sent: Monday, May 08, 2017 8:27 AM
To: 'Jacob Moore'
Subject: Pseudomonas chlororaphis strain AFS009 And PRIA Due dates

The new PRIA due date of June 21, 2017, for these two pending applications, EPA File Symbol 91197-G and petition 5F8410, was approved. Please let me know if you have any questions or concerns.

Regards,

Susanne Cerrelli
Regulatory Action Leader
Biopesticides Pollution Prevention Division
703-308-8077

Cerrelli, Susanne

From: Richard Keigwin <Keigwin.Richard@epamail.epa.gov> on behalf of Workflow Messenger <Workflow_Messenger@epamail.epa.gov>
Sent: Friday, May 05, 2017 11:12 AM
To: Keigwin, Richard; Cerrelli, Susanne
Subject: Recommendation of Division Directors Negotiated Due Dates has been completed by Richard Keigwin.

Recommendation of Division Directors Negotiated Due Dates has been completed by Richard Keigwin.

Author: Susanne Cerrelli
Chemical: Pseudomonas chlororaphis strain AFS009
Form Date: 05/04/2017
Decision #: 510007

Registration #:

Petition #: 5F8410

Original PRIA Due Date: 03/23/2017
Previous Negotiated Due Dates: 05/05/2017, , ,
Proposed New PRIA Due Date: 06/21/2017

Click on this link to access this form:
https://webforms.epa.gov/webforms/webformsadmin.nsf/formOpen?OpenAgent&UNID=3531374D7945DD998525811600 7AA3CC&USERDB=webforms/webformsapp.nsf

Recommendation of Division Directors
Negotiated Due Dates

Decision #: 510007	Registration #:	Petition #: 5F8410

☐ *See page 2 for additional registration entries*

Chemical Name: Pseudomonas chlororaphis strain AFS009

Fee Category: B590	**PRIA Decision Time Frame:** 17 months	
Submitted by: Susanne Cerrelli	**Branch:** OCSPP/OPP/BPPD	**Date:** 05/04/2017

Company: AFS009 Plant Protection, Inc.

Original PRIA Due Date: 03/23/2017	**Proposed New PRIA Due Date:** 06/21/2017

Previous Negotiated Due Dates: 05/05/2017

Is the "Fix" in-house? ☐ Yes ☐ No ☑ n/a **If not, date "Fix" expected:**

Negotiated Due Date Reason:

Additional Data Required	☐ Product Chemistry	☐ Toxicology	☐ Acute Tox	☐ Environmental	
	☐ Efficacy	☐ Ecological	☐ Residue	☐ Other	
Data Deficiencies	☐ Product Chemistry	☐ Acute Tox	☐ Efficacy	☐ Residue	☐ Toxicology
	☐ Environmental	☐ Ecological	☐ Labeling	☐ Other	☐ Not Submitted
Late Risk Assessment	☐ Human Health	☐ Ecological			
Interim Consideration	☐ Agency Initiated	☐ Registrant Initiated			

☐ CSF	☐ Public Process	☐ Risk Issues Environmental	☐ Risk Issues Human Health
☐ Impurities Review	☐ Label	☑ Administrative-FR Notice	☑ Other – Comment Field

Summary of Deficiency Type(s): ☐ **Not Submitted (N)** ☐ **Deficiencies (D)**

Product Chemistry: ☐ **Acute Tox:** ☐ **Efficacy:** ☐ **Labeling:** ☐ **Ecological Data:** ☐ **Other (deseribe):** ☐

Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated dne dates):

In an 04/06/2017 email, EPA contacted the agent and proposed an extension of the PRIA due date to 05/26/2017 because this tolerance exemption action was still be processed. Hearing nothing further after this correspondence, EPA sent a follow-up email to the agent on 04/10/2017. See the "Comment(s)" section on page 2 for additional details.

"75 Day" Letter sent? ☐ **Yes, Date sent** ☑ **No and reason for none?** *Add comments on page 2*

Rationale for Proposed Due Date:

Registrant notified that this is the last negotiation? ☐ **Yes** ☑ **Not Applicable**

Approve: ☑	**Disapprove:** ☐

If disapproved, action to be taken:

OD or DOD Signature: *CN=Richard Keigwin/OU=DC/O=USEPA/C=US*	**Date:** *05/05/2017*

Decision #:	Registration #:	Petition #:

Issue(s) (describe in detail):

Because of internal disagreement between science reviewers on some of the text related to the acute inhalation toxicity test done with the active ingredient (i.e., clinical signs vs. signs of toxicity) in the tolerance exemption documents, BPPD is still working on addressing comments from the Office of General Counsel. (*Note: The acute inhalation toxicity test has been classified as Toxicity Category IV, and the sign at issue was irregular respiration noted in the animals for 1-6 hours upon their removal from the test chamber; no mortalities were reported.) BPPD is continuing to work to resolve this issue as expeditiously as possible. After the tolerance exemption documents are finalized, they will then need to be routed to the Office Director for signature and sent to the Regulatory Coordination Staff for further processing

Comment(s):

Continued from "Interactions with Company" section on page 1 -
The agent responded the same day and said that he would call EPA the next day to discuss further. On 04/11/2017, EPA and the agent had a phone conversation, during which EPA explained the remaining tasks that needed to be completed for this action and the agent expressed concern over an extension of approximately 6 weeks because of his client potentially missing the growing season. The same day, the agent sent an email to EPA, agreeing to a new PRIA due date of 05/08/2017. On May 4, 2017 the RAL notified the Agent that the tolerance exemption and the related registration would not be issued by May 8, 2017. On May 4, 2017, after sending a rebuttal to the RAL concerning a suggested July 5, 2017 PRIA date, a request for June 21, 2017 PRIA date was emailed by the Agent.

Reason for not doing a 75-day deficiency letter -
At this time, there are no deficiencies that the applicant needs to address; thus, a 75-day deficieny letter is not warranted.

"Other - Comment Field" checked on page 1 -
See "Issue(s)" section above.

Audit Trail for

Recommendation of Division Directors Negotiated Due Dates

PDF Name: PRIAv5.pdf
Form Number: PRIA
Document Identifier: PRIA-17124181933-SC

SUBMITTED on 05/04/2017 at 06:23:54 PM by CN=Susanne Cerrelli/OU=DC/O=USEPA/C=US

APPROVED on 05/05/2017 at 10:26:30 AM by CN=Sharon Carlisle/OU=DC/O=USEPA/C=US

APPROVED on 05/05/2017 at 10:34:19 AM by CN=Robert Mcnally/OU=DC/O=USEPA/C=US

APPROVED AND COMPLETED on 05/05/2017 at 11:12:02 AM by CN=Richard Keigwin/OU=DC/O=USEPA/C=US

From: Jacob Moore
To: Kausch, Jeannine
Cc: Cerrelli, Susanne; Carlisle, Sharon; Mendelsohn, Mike
Subject: RE: EPA file symbol 91197-G-
Date: Tuesday, April 11, 2017 6:13:34 PM
Attachments: removed.txt

Jeannine,

Thank you again for discussing the timeline and PRIA due date for Howler. Please let me know if you have any additional questions or comments on the draft label.

We request that the renegotiated PRIA due date be May 8, 2017, understanding that all parties are working as hard as possible to finalize review and approval of the tolerance exemption and new product submission.

For an agricultural-use product like Howler, the spring season is a critical time to introduce the product to market and hopefully help growers appreciate the utility of using a new conventional alternative. A lot of the planning for the year is made during this period, and any movement we can have toward product approval is greatly appreciated.

Best Regards,

-Jacob

Jacob S. Moore | Regulatory Consultant
Technology Sciences Group Inc. (TSG)
712 Fifth Street, Suite A | Davis, CA 95616
Tel: 530-601-5064 | Fax: 530-757-1299 | jmoore@TSGUSA.com | skype: jacob_s_moore
www.TSGUSA.com

From: Jacob Moore
Sent: Monday, April 10, 2017 3:36 PM
To: 'Kausch, Jeannine' <Kausch.Jeannine@epa.gov>
Cc: Cerrelli, Susanne <Cerrelli.Susanne@epa.gov>; Carlisle, Sharon <Carlisle.Sharon@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>
Subject: RE: EPA file symbol 91197-G-

Hey Jeannine,

I just had a chat with them, and we're working on a response now. Hopefully we'll get an email back tomorrow (Tuesday) and I'll give you a ring to discuss.

Thank you,

-Jacob

Jacob S. Moore | Regulatory Consultant
Technology Sciences Group Inc. (TSG)
712 Fifth Street, Suite A | Davis, CA 95616
Tel: 530-601-5064 | Fax: 530-757-1299 | jmoore@TSGUSA.com | skype: jacob_s_moore
www.TSGUSA.com

From: Kausch, Jeannine [mailto:Kausch.Jeannine@epa.gov]
Sent: Monday, April 10, 2017 2:41 PM
To: Jacob Moore <JMoore@tsgusa.com>
Cc: Cerrelli, Susanne <Cerrelli.Susanne@epa.gov>; Carlisle, Sharon <Carlisle.Sharon@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>
Subject: FW: EPA file symbol 91197-G-

Hi Jacob,

As Susanne is out of the office this week, I am filling in for her in some respects. Did you hear anything further from AFS009 Plant Protection about pushing the current PRIA due dates for 91197-G and the associated petition (5F8410) out several weeks?

The PRIA due date is currently next Monday, and I will need to prepare paperwork for my management this week. Thus, it would be helpful to hear back from you on the new PRIA due date by Wednesday at the latest.

Thanks for your help, and please let me know if you have any questions.

Regards,
Jeannine

signature with logo - Jeannine

From: Cerrelli, Susanne
Sent: Thursday, April 06, 2017 12:25 PM
To: Jacob Moore <JMoore@tsgusa.com>

Cc: Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>; Kausch, Jeannine <Kausch.Jeannine@epa.gov>
Subject: RE: EPA file symbol 91197-G-

As requested I am emailing you an explanation of why we believe we may need additional time to issue a registration of EPA File symbol 91197-G, Howler.

- All tolerance exemptions are considered a regulatory action.
- Before a Tolerance exemption can be issued or published it will go through review. (All regulations are currently subject to review before publication.)
- The Tolerance exemption for *Pseudomonas chlororaphis* strain AFS009 will need to be published in the Federal Register before is goes in effect.
- Until the exemption is published in the Federal Regisrer the food use product, Howler, cannot be registered.

Although we are working to complete this by the April 17, 2017- PRIA date – we anticipate we will need to renegotiate the date to allow for the regulatory review and publication of the tolerance exemption as well as final review of the labels that you will be sending in this week.

If we could have a PRIA extension request it would assist us in finalizing this registration in the event that the tolerance exemption is not published by April 17, 2017.

We believe an extension request until May 26, 2017 for the petition and 91197-G would cover the additional time for regulatory review, and will do our best to publish the registration before that time.

If you have questions, please contact me at 703-308-8077.

Regards,

Susanne Cerrelli
Regulatory Action Leader
Biopesticides Pollution Prevention Division
703-308-8077

Cerrelli, Susanne

From: Richard Keigwin <Keigwin.Richard@epamail.epa.gov> on behalf of Workflow Messenger <Workflow_Messenger@epamail.epa.gov>
Sent: Monday, April 17, 2017 1:58 PM
To: Hollis, Linda; Bryceland, Andrew; Nesci, Kimberly; Reynolds, Alan; Borges, Shannon; Burnett, Gina; Carlisle, Sharon; McNally, Robert; Whitaker, Renae; Leahy, John; Layne, Arnold; Keigwin, Richard; Cerrelli, Susanne; Whitaker, Renae; Carlisle, Sharon; Burnett, Gina; Borges, Shannon; Reynolds, Alan; Nesci, Kimberly; Bryceland, Andrew; Hollis, Linda; Leahy, John; McNally, Robert; Keigwin, Richard; Layne, Arnold
Subject: Recommendation of Division Directors Negotiated Due Dates has been finished by Richard Keigwin.

The PRIA Recommendation of Division Directors Negotiated Due Dates has been completed and saved in WebForms.

Author: Jeannine Kausch
Chemical: Pseudomonas chlororaphis strain AFS009
Form Date: 04/13/2017
Decision #: 510005

Registration #: 91197-G

Petition #:

Original PRIA Due Date: 04/17/2017
Previous Negotiated Due Dates: , , ,
Proposed New PRIA Due Date: 05/08/2017

Click on this link to access this form:
https://webforms.epa.gov/webforms/webformsadmin.nsf/formOpen?OpenAgent&UNID=D3A7F8683EB7B1098525810100 5BEB9C&USERDB=webforms/webformsapp.nsf

Recommendation of Division Directors
Negotiated Due Dates

Decision #: 510005	Registration #: 91197-G	Petition #:

☐ *See page 2 for additional registration entries*

Chemical Name: Pseudomonas chlororaphis strain AFS009

Fee Category: B590 | **PRIA Decision Time Frame:** 17 months

Submitted by: Jeannine Kausch | **Branch:** OCSPP/OPP/BPPD | **Date:** 04/13/2017

Company: AFS009 Plant Protection, Inc.

Original PRIA Due Date: 04/17/2017 | **Proposed New PRIA Due Date:** 05/08/2017

Previous Negotiated Due Dates:

Is the "Fix" in-house? ☐ Yes ☐ No ☑ n/a | **If not, date "Fix" expected:**

Negotiated Due Date Reason:

Additional Data Required	☐ Product Chemistry	☐ Toxicology	☐ Acute Tox	☐ Environmental	
	☐ Efficacy	☐ Ecological	☐ Residue	☐ Other	
Data Deficiencies	☐ Product Chemistry	☐ Acute Tox	☐ Efficacy	☐ Residue	☐ Toxicology
	☐ Environmental	☐ Ecological	☐ Labeling	☐ Other	☐ Not Submitted
Late Risk Assessment	☐ Human Health	☐ Ecological			
Interim Consideration	☐ Agency Initiated	☐ Registrant Initiated			

☐ CSF	☐ Public Process	☐ Risk Issues Environmental	☐ Risk Issues Human Health
☐ Impurities Review	☐ Label	☑ Administrative-FR Notice	☑ Other – Comment Field

Summary of Deficiency Type(s): ☐ **Not Submitted (N)** ☐ **Deficiencies (D)**

Product Chemistry: ☐ **Acute Tox:** ☐ **Efficacy:** ☐ **Labeling:** ☐ **Ecological Data:** ☐ **Other (describe):** ☐

Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates):

In an 04/06/2017 email, EPA contacted the agent and proposed an extension of the PRIA due date to 05/26/2017 because the tolerance exemption associated with this action was still be processed. Hearing nothing further after this correspondence, EPA sent a follow-up email to the agent on 04/10/2017. See the "Comment(s)" section on page 2 for additional details.

"75 Day" Letter sent? ☐ **Yes, Date sent** ☑ **No and reason for none?** *Add comments on page 2*

Rationale for Proposed Due Date: To finish processing the associated tolerance action & make decision.

Registrant notified that this is the last negotiation? ☐ **Yes** ☑ **Not Applicable**

Approve: ☑ | **Disapprove:** ☐

If disapproved, action to be taken:

OD or DOD Signature: *CN=Richard Keigwin/OU=DC/O=USEPA/C=US* | **Date:** *04/17/2017*

Decision #:	Registration #:	Petition #:

Issue(s) (describe in detail):

Because of internal disagreement between science reviewers on some of the text related to the acute inhalation toxicity test done with the active ingredient (i.e., clinical signs vs. signs of toxicity) in the associated tolerance exemption documents, BPPD is still working on addressing comments from the Office of General Counsel. (*Note: The acute inhalation toxicity test has been classified as Toxicity Category IV, and the sign at issue was irregular respiration noted in the animals for 1-6 hours upon their removal from the test chamber; no mortalities were reported.) BPPD is continuing to work to resolve this issue as expeditiously as possible. After the tolerance exemption documents are finalized, they will then need to be routed to the Office Director for signature and sent to the Regulatory Coordination Staff for further processing. Part of this processing involves review by the Office of Policy (OP), and the review time seems to have varied anywhere from a few weeks to a few months. This action cannot be approved until the tolerance exemption final rule clears OP and publishes in the Federal Register.

Comment(s):

Continued from "Interactions with Company" section on page 1 -

The agent responded the same day and said that he would call EPA the next day to discuss further. On 04/11/2017, EPA and the agent had a phone conversation, during which EPA explained the remaining tasks that needed to be completed for this action and the agent expressed concern over an extension of approximately 6 weeks because of his client potentially missing the growing season. The same day, the agent sent an email to EPA, agraeing to a new PRIA due date of 05/08/2017.

Reason for not doing a 75-day deficiency letter -

At this time, there are no deficiencies that the applicant needs to address; thus, a 75-day deficieny letter is not warranted.

"Other - Comment Field" checked on paga 1 -

See "Issue(s)" section above.

Audit Trail for

Recommendation of Division Directors Negotiated Due Dates

PDF Name: PRIAv5.pdf
Form Number: PRIA
Document Identifier: PRIA-17103124400-JK

SUBMITTED on 04/13/2017 at 07:00:56 PM by CN=Jeannine Kausch/OU=DC/O=USEPA/C=US

APPROVED on 04/17/2017 at 11:15:57 AM by CN=Sharon Carlisle/OU=DC/O=USEPA/C=US

APPROVED on 04/17/2017 at 01:49:25 PM by CN=Robert Mcnally/OU=DC/O=USEPA/C=US

APPROVED AND COMPLETED on 04/17/2017 at 01:57:55 PM by CN=Richard Keigwin/OU=DC/O=USEPA/C=US

Privacy interest information

Cerrelli, Susanne

From: Kough, John
Sent: Tuesday, April 11, 2017 3:57 PM
To: Gagliardi, Joel; Mendelsohn, Mike; Kausch, Jeannine; Huskey, Angela; Hartman, Mark; Cerrelli, Susanne
Subject: RE: Discuss OGC Comments on P. chlororaphis [redacted] Conf Code [redacted]

Thanks for the quick turnaround on this, Joel. Hopefully, we will not need the added references for your write-up.

John K.

From: Gagliardi, Joel
Sent: Tuesday, April 11, 2017 3:21 PM
To: Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>; Kausch, Jeannine <Kausch.Jeannine@epa.gov>; Kough, John <Kough.John@epa.gov>; Huskey, Angela <Huskey.Angela@epa.gov>; Hartman, Mark <Hartman.Mark@epa.gov>; Cerrelli, Susanne <Cerrelli.Susanne@epa.gov>
Subject: RE: Discuss OGC Comments on P. chlororaphis [redacted] Conf Code [redacted]

I've addressed the reason for waiving the inhalation and injection toxicity/pathogenicity studies. I could add references if you think that people would want them, but I did not here.

As I stated before interpretation of toxicity/pathogenicity studies is left to the reviewer but it is discussed in some of the guidelines and 885.3000 and in previous SAP materials and pre-ambles to the final rule. The guidelines direct the reviewer to note any "significant toxicity" and there is not general guidance on how to assess infectivity or what pathogenicity is.

I know. But there is not general or specific guidance provided by EPA.

-----Original Appointment-----
From: Mendelsohn, Mike
Sent: Thursday, April 06, 2017 5:26 PM
To: Mendelsohn, Mike; Gagliardi, Joel; Kausch, Jeannine; Kough, John; Huskey, Angela; Hartman, Mark; Cerrelli, Susanne
Subject: Discuss OGC Comments on P. chlororaphis [redacted] Conf Code [redacted]
When: Tuesday, April 11, 2017 1:30 PM-2:30 PM (UTC-05:00) Eastern Time (US & Canada).
Where: DCRoomPYS8771/Potomac-Yard-One

Pages 37-44 - Draft FR Notice - *Internal deliberative information* -- *Privileged attorney-client communication*

From: Jacob Moore
To: Kausch, Jeannine
Cc: Cerrelli, Susanne; Carlisle, Sharon; Mendelsohn, Mike
Subject: RE: EPA file symbol 91197-G-
Date: Tuesday, April 11, 2017 6:13:34 PM
Attachments: removed.txt

Jeannine,

Thank you again for discussing the timeline and PRIA due date for Howler. Please let me know if you have any additional questions or comments on the draft label.

We request that the renegotiated PRIA due date be May 8, 2017, understanding that all parties are working as hard as possible to finalize review and approval of the tolerance exemption and new product submission.

For an agricultural-use product like Howler, the spring season is a critical time to introduce the product to market and hopefully help growers appreciate the utility of using a new conventional alternative. A lot of the planning for the year is made during this period, and any movement we can have toward product approval is greatly appreciated.

Best Regards,

-Jacob

Jacob S. Moore | Regulatory Consultant
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Tel: 530-601-5064 | Fax: 530-757-1299 | jmoore@TSGUSA.com | skype: jacob_s_moore
www.TSGUSA.com

From: Jacob Moore
Sent: Monday, April 10, 2017 3:36 PM
To: 'Kausch, Jeannine' <Kausch.Jeannine@epa.gov>
Cc: Cerrelli, Susanne <Cerrelli.Susanne@epa.gov>; Carlisle, Sharon <Carlisle.Sharon@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>
Subject: RE: EPA file symbol 91197-G-

Hey Jeannine,

I just had a chat with them, and we're working on a response now. Hopefully we'll get an email back tomorrow (Tuesday) and I'll give you a ring to discuss.

Thank you,

-Jacob

Jacob S. Moore | Regulatory Consultant
Technology Sciences Group Inc. (TSG)
712 Fifth Street, Suite A | Davis, CA 95616
Tel: 530-601-5064 | Fax: 530-757-1299 | jmoore@TSGUSA.com | skype: jacob_s_moore
www.TSGUSA.com

From: Kausch, Jeannine [mailto:Kausch.Jeannine@epa.gov]
Sent: Monday, April 10, 2017 2:41 PM
To: Jacob Moore <JMoore@tsgusa.com>
Cc: Cerrelli, Susanne <Cerrelli.Susanne@epa.gov>; Carlisle, Sharon <Carlisle.Sharon@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>
Subject: FW: EPA file symbol 91197-G-

Hi Jacob,

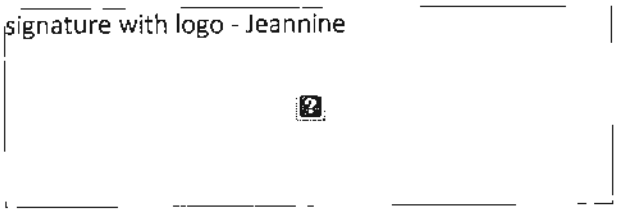
As Susanne is out of the office this week, I am filling in for her in some respects. Did you hear anything further from AFS009 Plant Protection about pushing the current PRIA due dates for 91197-G and the associated petition (5F8410) out several weeks?

The PRIA due date is currently next Monday, and I will need to prepare paperwork for my management this week. Thus, it would be helpful to hear back from you on the new PRIA due date by Wednesday at the latest.

Thanks for your help, and please let me know if you have any questions.

Regards,
Jeannine

signature with logo - Jeannine



From: Cerrelli, Susanne
Sent: Thursday, April 06, 2017 12:25 PM
To: Jacob Moore <JMoore@tsgusa.com>

Cc: Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>; Kausch, Jeannine <Kausch.Jeannine@epa.gov>
Subject: RE: EPA file symbol 91197-G-

As requested I am emailing you an explanation of why we believe we may need additional time to issue a registration of EPA File symbol 91197-G, Howler.

- All tolerance exemptions are considered a regulatory action.
- Before a Tolerance exemption can be issued or published it will go through review. (All regulations are currently subject to review before publication.)
- The Tolerance exemption for *Pseudomonas chlororaphis* strain AFS009 will need to be published in the Federal Register before is goes in effect.
- Until the exemption is published in the Federal Register the food use product, Howler, cannot be registered.

Although we are working to complete this by the April 17, 2017- PRIA date – we anticipate we will need to renegotiate the date to allow for the regulatory review and publication of the tolerance exemption as well as final review of the labels that you will be sending in this week.

If we could have a PRIA extension request it would assist us in finalizing this registration in the event that the tolerance exemption is not published by April 17, 2017.

We believe an extension request until May 26, 2017 for the petition and 91197-G would cover the additional time for regulatory review, and will do our best to publish the registration before that time.

If you have questions, please contact me at 703-308-8077.

Regards,

Susanne Cerrelli
Regulatory Action Leader
Biopesticides Pollution Prevention Division
703-308-8077

Pages 49-56 - Draft FR Notice - *Internal deliberative information* -- *Privileged attorney-client communication*

as meeting the 110(a)(2)(D)(i) prong 1 requirement for the 2008 ozone NAAQS. This proposed action supersedes the EPA's May 10, 2016 proposed disapproval of prong 1 of the Utah SIP for the 2008 ozone NAAQS. *See* 81 FR 28807.

IV. Proposed Action

The EPA is proposing to approve the section 110(a)(2)(D)(i)(I) prong 1 portion of Utah's January 31, 2013 submittal and the December 22, 2015 submittal with respect to the 2008 ozone NAAQS. The EPA is soliciting public comments on this proposed action and will consider public comments received during the comment period.

V. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve state actions, provided that they meet the criteria of the Clean Air Act. Accordingly, this proposed action merely proposes approval of state law as meeting federal requirements; this proposed action does not propose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, Oct. 4, 1993);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- Does not provide the EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

The SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: December 12, 2016.

Richard D. Buhl,

Acting Regional Administrator, Region 8.

[FR Doc. 2016–30462 Filed 12–19–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2015–0032; FRL–9956–04]

Receipt of Several Pesticide Petitions Filed for Residues of Pesticide Chemicals in or on Various Commodities

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of filing of petitions and request for comment.

SUMMARY: This document announces EPA's receipt of several initial filings of pesticide petitions requesting the establishment or modification of regulations for residues of pesticide chemicals in or on various commodities.

DATES: Comments must be received on or before January 19, 2017.

ADDRESSES: Submit your comments, identified by the Docket Identification (ID) Number and the Pesticide Petition Number (PP) of interest as shown in the body of this document, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.* Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Robert McNally, Biopesticides and Pollution Prevention Division (7511P), main telephone number: (703) 305–7090, email address: *BPPDFRNotices@epa.gov;* or Michael Goodis, Registration Division (7505P), main telephone number: (703) 305–7090, email address: *RDFRNotices@epa.gov.* The mailing address for each contact person is: Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001. As part of the mailing address, include the contact person's name, division, and mail code. The division to contact is listed at the end of each pesticide petition summary.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT** for the division listed at the

end of the pesticide petition summary of interest.

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information tbat you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html.*

3. *Environmentol justice.* EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low-income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, EPA seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticides discnssed in this document, compared to the geueral popnlation.

II. What action is EPA taking?

EPA is announcing its receipt of several pesticide petitions filed under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, reqnesting the establishment or modificatiou of regulations in 40 CFR part 180 for residues of pesticide chemicals in or ou various food commodities. EPA is taking public comment on the requests before responding to the petitioners. EPA is not proposing any particular actiou at this time. EPA has determined that the pesticide petitions described in this documeut contain the data or information prescribed in FFDCA section 408(d)(2), 21 U.S.C. 346a(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the pesticide petitious. After considering the public comments, EPA intends to evaluate whether and what action may be warranted. Additional data may be needed before EPA can make a final determination on these pesticide petitions.

Pursnant to 40 CFR 180.7(f), a summary of each of the petitions that are the subject of this document, prepared by the petitioner, is included in a docket EPA has created for each rulemaking. The docket for each of the petitions is available at *http://www.regulotions.gov.*

As specified iu FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), EPA is publishing notice of the petitions so that the public has an opportunity to comment on these requests for the establishment or modification of regulations for residues of pesticides in or on food commodities. Further information on the petitions may be obtained through the petition summaries referenced in this unit.

New Tolerances

1. *PP 5E8440.* (EPA–HQ–OPP–2016–0392). Dow AgroSciences LLC, 9330 Zionsville Rd., Indianapolis, IN 46268, requests to establish tolerances in 40 CFR part 180 without a U.S. registration for residues of the fungicide fenpicoxomid (XDE 777) in or on the raw agricultural commodities banana at 0.1 parts per million (ppm), rye at 0.7 ppm, and wheat at 0.7 ppm; and residues of fenpicoxomid plus its metabolite X12326349, expressed as fenpicoxomid equivalents, in or on meat and fat from cattle, goats, and sheep at 0.01 ppm; and meat byproducts of cattle, goats, and sheep at 0.02 ppm. The Method S12–01537, "XDE 777 and its Metabolite X642188—Validation of the Method for the Determination of XDE 777 and its Metabolite X642188 in Crops by LC MS/MS," was used for the analysis of XDE 777 and its metabolite X642188 in the plant materials. Samples were analyzed by liqnid chromatography using a Phenomenex Luna C18 column coupled with positive-ion electrospray tandem mass spectrometry (LC/MS/MS), monitoring two MS/MS transitions characteristic of each analyte. Contact: RD.

2. *PP 5F8403.* (EPA–HQ–OPP–2016–0560). Dow AgroSciences LLC, 9330 Zionsville Rd., Indianapolis, IN 46268, requests to establish tolerances in 40 CFR part 180 for residues of the herbicide florpyrauxifen-benzyl (2-Pyridinecarboxylic acid, 4-amino-3-chloro-6-(4-chloro-2-fluoro-3-methoxyphenyl)-5-flnoro-, phenylmethyl ester) and florpyrauxifen (metabolite; 2-Pyridinecarboxylic acid, 4-amino-3-chloro-6-(4-chloro-2-fluoro-3-methoxyphenyl)-5-fluoro-) in or on the raw agricultural commodities rice, grain (dehulled) at 0.01 ppm; rice, grain at 0.2 ppm; fisb, freshwater at 2 ppm; shellfish, crustacean at 0.5 ppm; and shellfish, mollusk at 9 ppm. The liquid chromatography with tandem mass spectrometry analytical method 130794.1 is used to validete rice grain and straw matrices. A separate liquid chromatography with taudem mass spectrometry analytical method 130794.02 is used to validate matrices of rice processed fractions. Contact: RD.

3. *PP 5F8417.* (EPA–HQ–OPP–2015–0787). K–I Chemical USA, Inc., 11 Martine Ave., Suite 970, White Plains, NY 10606, requests to establish tolerauces in 40 CFR 180.659 for residues of the herbicide pyroxasulfone [3-[(5-(difluoromethoxy)-1-methyl-3-(trifluoromethyl) pyrazole-4-ylmethylsulfonyl]-4,5-dihydro-5,5-dimethyl-1,2-oxazole) and its metabolites in or on dried shelled peas and beans (crop subgroup 6C) at 0.15 ppm, pea hay at 0.40 ppm, pea vines at 0.20 ppm, cowpea hay at 0.07 ppm, cowpea forage at 3.0 ppm flax at 0.07 ppm, peauut at 0.20 ppm, peanut hay at 3.0 ppm, peanut meal at 0.40 ppm, and vegetable, foliage of legume, except soybean, subgroup 07A at 3.0 ppm. The LC/MS/MS has been proposed to enforce the tolerance expressiou for pyroxasulfone. Contact: RD.

4. *PP 6E8505.* (EPA–HQ–OPP–2016–0049). Interregional Research Project No. 4 (IR–4), Rutgers, The State University of New Jersey, 500 College Rd. East, Suite 201W, Princeton, NJ 08540, requests to establish tolerances in 40 CFR 180.685 for residues of the fungicide oxathiapiprolin, 1-[4-[4-[5-(2,6-difluorophenyl)-4,5-dihydro-3-isoxazolyl]-2-thiazolyl]-1-piperidinyl]-2-[5-methyl-3-(trifluoromethyl)-1H-pyrazol-1-yl]-ethauoue, in or on cacao bean, bean at 0.10 ppm; cacao bean, chocolate at 0.15 ppm; cacao bean, cocoa powder at 0.15 ppm; and cacao bean, roasted bean at 0.15 ppm. Adequate analytical methodology, high-pressure liquid chromatography with tandem mass spectrometry (MS/MS) detection, is available for tolerance enforcement purposes. Contact: RD.

5. *PP 6E8511.* (EPA–HQ–OPP–2016–0587). IR–4, Rutgers, The State University of New Jersey, 500 College Rd. East, Suite 201W, Princeton, NJ 08540, requests to establish e tolerance in 40 CFR 180.444 for residues of sulfur dioxide, iucluding its metabolites and degradates, in or on fig at 25 ppm. An analytical enforcement method, the

Monier-Williams Procedure for Sulfites (21 CFR part 101 Appendix A), is available for enforcement of tolerances for snlfites in food. Contact: RD.

6. *PP 6F8507.* (EPA–HQ–OPP–2016–0573). Isagro S.p.A. d/b/a Isagro USA, Inc., 430 Davis Dr., Suite 240, Morrisville, NC 27560, requests to establish tolerances in 40 CFR 180.557 for residues of the fungicide tetraconazole in or on barley at 0.3 ppm; crop group 16, forage, fodder, and straw of cereal grains group (except corn) at 8.0 ppm; dried shelled pea and bean (except soybean) snbgroup 6C, hay at 8.0 ppm; dried shelled pea and bean (except soybean) subgroup 6C, seed at 0.15 ppm; dried shelled pea and bean (except soybean) subgroup 6C, vine at 2.0 ppm; rapeseed crop subgroup 20A at 0.9 ppm; and wheat at 0.1 ppm. The adequate enforcement methodology (capillary gas chromatography with electron capture detector (GC/ECD)), as well as a QuEChERS multi-residue method (LC/MS–MS detection), is used to measure and evaluate the chemical tetraconazole. Contact: RD.

Amended Tolerance

1. PP 4F8258. (EPA–HQ–OPP–2014–0357). DuPont Crop Protection, P.O. Box 30, Newark, DE 19714–0030, requests to amend the tolerance in 40 CFR 180.672 for residues of the insecticide cyantraniliprole in or on vegetable, cucurbit (group 9) at 0.70 ppm. Adeqnate analytical methodology, high-pressure liquid chromatography with tandem mass spectrometry (MS/MS) detection, is available for tolerance enforcement purposes. Contact: RD.

2. *PP 6F8476.* (EPA–HQ–OPP–2016–0360). Albaugh, LLC, P.O. Box 2127, Valdosta, GA 31604, requests to amend the tolerances in 40 CFR 180.441(a)(1) for the residues of the herbicide quizalofop ethyl, including its metabolites and degradates, in or on wheat, bran at 0.40 ppm; wheat, forage et 2.0 ppm; wheat, germ at 0.40 ppm; wheat, hay at 2.0 ppm; wheat, milled byproducts at 0.40 ppm; and wheat, straw at 0.80 ppm. The modified Morse Method-147 is used to measure and evaluate the chemical quizalofop-P-ethyl and quizalofop-P acid, convertible to 6-chloro-2-methoxyquinoxaline (MeCHQ). Contact: RD.

New Tolerance Exemptions

1. *PP IN–10970.* (EPA–HQ–OPP–2016–0606). AgroFresh Inc., 400 Arcola Rd., P.O. Box 7000, Collegeville, PA 19426, requests to establish an exemption from the requirement of a tolerance for residues of polyglycerol polyricinoleic acid (CAS Reg. No. 29894–35–7) with a minimum number average molecular weight (in amu) of 2,000 when used as an inert ingredient in pesticide formulations under 40 CFR 180.960. The petitioner believes no analytical method is needed because it is not required for an exemption from the reqnirement of a tolerance. Contact: RD.

2. *PP IN–10984.* (EPA–HQ–OPP–2016–0617). Spring Trading Company, on behalf of Ethox Chemicals, LLC, 1801 Perimeter Rd., Greenville, SC 29605, requests to establish an exemption from the requirement of a tolerance for residues of octadecanoic acid, 12-hydroxy-, homopolymer, ester with α, α′,α″-1,2,3-propanetriyltris[ω-hydroxypoly(oxy-1,2-ethanediyl)] (CAS Reg. No. 1939051–18–9) with a minimum number average molecular weight (in amu) of 5,000 when used as an inert ingredient in pesticide formulations under 40 CFR 180.960. The petitioner believes no analytical method is needed because it is not required for an exemption from the requirement of a tolerance. Contact: RD.

3. *PP 5F8410.* (EPA–HQ–OPP–2016–0284). AFS009 Plant Protection, Inc., 104 T.W. Alexander Dr., Building 18, Research Triangle Park, NC 27709, requests to establish an exemption from the requirement of a tolerance in 40 CFR part 180 for residues of the fungicide *Pseudomanas chlororaphis* strain AFS009 in or on all food commodities. The petitioner believes no analytical method is needed because it is expected that, when nsed as proposed, *Pseudomonas chlororaphis* strain AFS009, would not result in residues that are of toxicological concern. Note: In the **Federal Register** of June 22, 2016 (81 FR 40594) (FRL–9947–32), EPA announced the filing of this petition to establish an exemption from the requirement of e tolerance for residues of *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009 in or on all food commodities. Since that time, the petitioner provided additional data on the identity of the active ingredient to EPA. After reviewing these deta, EPA now considers the correct identity of the active ingredient to be *Pseudomonas chlororaphis* strain AFS009 and not *Pseudamonas chlororaphis* subsp. *ourantiaca* strain AFS009. In order to give the public an opportunity to comment on this new information, EPA is republishing its receipt of this tolerance exemption petition filing with an updated and accurate description. Contact: BPPD.

4. *PP 6F8485.* (EPA–HQ–OPP–2016–0608). BASF Corporation, 26 Davis Dr., Research Triangle Park, NC 27709, requests to establish an exemption from the requirement of a tolerance in 40 CFR part 180 for residues of the insecticide *Beauveria bassiana* strain PPRI 5339 in or on all food commodities. The petitioner believes no analytical method is needed because it is expected that, when used as proposed, *Beauveria bassiana* strain PPRI 5339, would not result in residues that are of toxicological concern. Contact: BPPD.

Amended Tolerance Exemption

1. *PP 6F8481.* (EPA–HQ–OPP–2016–0578). Verdesian Life Sciences U.S., LLC, 1001 Winstead Dr., Snite 480, Cary, NC 27513, reqnests to amend an exemption from the raquirement of a tolerance in 40 CFR 180.1210 for residues of the systemic fungicide/systemic acquired resistance (SAR) inducer calcium salts of phosphorous acid in or on all food commodities when used as an agricultural fungicide and in or on potetoes when applied as a post-harvest treatment at 35,600 ppm or less phosphorous acid. The two analytical methods available to EPA for the detection and measurement of the pesticide residues are the modified AOAC Method 958.01 and the modified AOAC Method 965.09. Contact: BPPD.

Authority: 21 U.S.C. 346a.

Dated: December 9, 2016.

Robert McNally,

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

[FR Doc. 2016–30647 Filed 12–19–16; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 224

[Docket No. 141216999–6999–02]

RIN 0648–XD669–X

Endangered and Threatened Wildlife and Plants: Notice of 12-Month Finding on a Petition To List the Gulf of Mexico Bryde's Whale as Endangered Under the Endangered Species Act (ESA); Correction

AGENCY: National Merine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule; correction.

SUMMARY: NMFS published in the **Federal Register** on December 8, 2016, a document proposing to list the Gulf of Mexico Bryde's whale as an endangered species under the Endangered Species Act of 1973 (ESA). This document

Cerrelli, Susanne

From: Amy Roberts <ARoberts@TSGUSA.COM>
Sent: Friday, October 21, 2016 7:18 PM
To: Cerrelli, Susanne
Cc: Kausch, Jeannine; Carlisle, Sharon
Subject: RE: Howler new ais - PRIA timing
Attachments: Pseudomonas chlororaphis strain AFS009 tolerance exemption petition - updated 10-21-2016.doc; NOF - Pseudomonas chlororaphis strain AFS009 tolerance exemption petition - updated October 21 2016.dot

Importance: High

Hi Susanne:

Attached is a revised petition and electronic notice of filing for your use.

I understand the below, but do question the need to reissue the Notice of Filing. The ingredient will have the same PC Code and we are not changing the species, just taking a step back from the subspecies. I don't understand why EPA needs to issue a new NOF. That seems very immaterial and unnecessary.

Regarding the PRIA date, let me talk to the registrant. I know one question they will raise is March 1 is fine for the food use, but can the non-food use (turf and ornamentals) issue earlier so they can target that early season turf.

Regards,

Amy Plato Roberts | Senior Regulatory Consultant
Technology Sciences Group Inc. (TSG)
1150 18th Street NW, Suite 1000 | Washington, DC 20036 USA
Tel: 208.788.0217 | Fax: 202.872.0745 | Email: aroberts@TSGUSA.com **| Skype: ARobertsTSG**
Visit us at www.TSGUSA.com

From: Cerrelli, Susanne [mailto:Cerrelli.Susanne@epa.gov]
Sent: Thursday, October 20, 2016 12:26 PM
To: Amy Roberts
Cc: Kausch, Jeannine; Carlisle, Sharon
Subject: RE: Howler new ais - PRIA timing

Dear Amy Roberts:

I am regretting not responding to you earlier. The time line you proposed is optimistic as we received many changes to the submission very late in the process. We are committed to getting these PRIA actions quickly. My earliest estimate is March 1, 2017 and that assumes no delays for snow closures, staff vacations, and no additional comments to address in the docket and a quick resolution of any risk issues that may be identified.

One item would help me I need an updated petition for the active ingredient that lacks the subspecies identification. I have been advised that I need to reissue the Notice of receipt and the Notice of filing for the AI with the new name listed. You can use the same old petition and just delete that subspecies text.

I likely have confused you. Please let me know if you have any questions.
I regret any inconvenience. I will get back to you about your other inquiries in a separate email.

Regards,

Susanne Cerrelli
Regulatory Action Leader
Biopesticides Pollution Prevention Division
703-308-8077

From: Amy Roberts [mailto:ARoberts@TSGUSA.COM]
Sent: Thursday, October 20, 2016 5:57 AM
To: Carlisle, Sharon <Carlisle.Sharon@epa.gov>; Kausch, Jeannine <Kausch.Jeannine@epa.gov>; Cerrelli, Susanne <Cerrelli.Susanne@epa.gov>
Subject: Howler new ais - PRIA timing

Hi ShaRon:

AFS009 Plant Protection Inc (AgBiome) is aware that the Agency is going to need some additional time for the final approval, docket and public participation piece. Having said that, they an timing plea/request on the T&O product around early season turf. For the T&O product, the really need it by mid-to late January to be able to begin to market for that early season turf area. So, they wanted provide the Agency with the below comments just on that.

We are extremely hopeful that a Federal approval for Howler will be completed by mid-January. The majority of State registrations will be a minimum of 30 days while others will be longer. A mid-January approval would result in state registrations for the majority of States by late February. Howler's primary application and pest management strengths are related to early season diseases control. Federal registration after Feb-1 would likely result in Howler, an already OMRI listed material, not being available to turf-managers for the 2017 season.

With the safety factor of Howler, the differing Modes of Action from all currently registered fungicides, and the environmentally friendly nature of the product, Howler is a product of critical need to producers. The primary fungicides being utilized have numerous human-safety issues for homeowners and pets, pesticide residue levels, worker safety and use restrictions, re-entry periods, pre-harvest intervals, considerable reports of resistance, and some under significant scrutiny such as the azoles which are known endocrine disrupters. Howler after extensive University field testing has tremendous support from the academic community who have seen the levels of efficacy comparable to conventional chemical fungicides.

For human safety, environmental concern, resistance management, reduced agricultural chemical use, and proper IPM, Howler is a product that is critically required in the 2017 growing season.

When you all are ready to talk about the PRIA date, let me know. I am on travel thru October 27, but available by email the whole time.

Best regards,

Amy Plato Roberts | Senior Regulatory Consultant
Technology Sciences Group Inc. (TSG)
1150 18th Street NW, Suite 1000 | Washington, DC 20036 USA
Tel: 208.788.0217 | Fax: 202.872.0745 | Email: aroberts@TSGUSA.com | Skype: ARobertsTSG
Visit us at www.TSGUSA.com

See us –

October 24-26, Annual Biocontrol Industry Meeting (ABIM) in Basel, Switzerland
November 15-17, Biocontrol LATAM in Campinas, São Paulo, Brasil

EPA BIOPESTICIDES AND POLLUTION PREVENTION DIVISION COMPANY NOTICE OF FILING FOR PESTICIDE PETITIONS PUBLISHED IN THE FEDERAL REGISTER

EPA Biopesticides and Pollution Prevention Division contact: ShaRon Carlisle; (703) 308-6427

INSTRUCTIONS: **Please utilize this outline in preparing the pesticide petition. In cases where the outline element does not apply, please insert "NA-Remove" and maintain the outline. Please do not change the margins, font, or format in your pesticide petition. Simply replace the instructions that appear in green, i.e., "[insert company name]," with the information specific to your action.**

SUBMISSION: **E-mail the completed template to: hollis.linda@epa.gov.**

TEMPLATE:

AFS009 Plant Protection, Inc. (EPA Co. No. 91197)

[Insert petition number]

EPA has received a pesticide petition **([insert petition number])** from AFS009 Plant Protection, Inc. (EPA Co. No. 91197), 104 T.W. Alexander Drive, Building 18, Research Triangle Park, NC 27709 proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish an exemption from the requirement of a tolerance for microbial pesticide *Pseudomonas chlororaphis* strain AFS009.

Pursuant to section 408(d)(2)(A)(i) of FFDCA, as amended, AFS009 Plant Protection, Inc. (EPA Co. No. 91197) has submitted the following summary of information, data, and arguments in support of their pesticide petition. This summary was prepared by AFS009 Plant Protection, Inc. (EPA Co. No. 91197) and EPA has not fully evaluated the merits of the pesticide petition. The summary may have been edited by EPA if the terminology used was unclear, the summary contained extraneous material, or the summary unintentionally made the reader conclude that the findings reflected EPA's position and not the position of the petitioner.

I. AFS009 Plant Protection, Inc. (EPA Co. No. 91197) Petition Summary

[Insert petition number]

A. Product Name and Proposed Use Practices

Product Name: **Howler™ Technical (100% ai; TGAI) – EPA File Symbol 91197-R**
Howler™ (50% ai; EP) – EPA File Symbol 91197-G

Proposed Use Practice: Howler™ Technical is a 100% ai Technical Grade Active Ingredient (TGAI) of *Pseudomonas chlororaphis* strain AFS009 and is proposed for manufacturing use only, for further formulation into registered end-use products.

Howler™ is a 50% ai is formulated end-use product for use on growing plants and crops to control plant diseases including *Rhizoctonia, Pythium, Fusarium, Phytophthora* and *Botrytis.* Howler™ may be mixed with water and applied as a foliar spray, soil drench, in furrow spray, transplant spray or dip, cuttings or bare root dip, hydroponic or chemigation application in greenhouse, agricultural field, turf and ornamental and home and garden use sites.

B. Product Identity/Chemistry

1. *Identity of the pesticide and corresponding residues.* *Pseudomonas chlororaphis* strain AFS009 (CAS No. Not applicable).

Pseudomonas chlororaphis is a common bacterium identified primarily in the soil. *Pseudomonas chlororaphis* is a Gram-negative, rod-shaped bacteria with one or more flagella for motility. Information regarding the name, identity and composition has been submitted to EPA and can be found in MRID No. 495680-01.

Like other *Pseudomonas chlororaphis* strains *Pseudomonas chlororaphis* strain AFS009 is a plant-colonizing bacteria which controls fungal diseases by several modes of action, including competition and production of a variety of metabolites which are inhibitory to the fungi. (MRID No. 495680-01).

2. *Magnitude of residues at the time of harvest and method used to determine the residue.* **NA-Remove**

3. *A statement of why an analytical method of detecting and measuring the levels of the pesticide residue are not needed.* An analytical method for residues is not applicable. It is expected that, when used as proposed, *Pseudomonas chlororaphis* strain AFS009, would not result in residues that are of toxicological concern.

C. Mammalian Toxicological Profile

Studies to evaluate the safety to mammals were conducted on the technical grade active ingredient (TGAI) and are summarized as follows:

1. Acute Oral Toxicity/Pathogenicity Study in Rats (OCSPP 885.3050): Howler™ Technical (100% *Pseudomonas chlororaphis* strain AFS009) was not toxic or pathogenic in rats following acute oral exposure to a concentrate of 3.73 x 10^9 (MRID No. 495680-02). The MPCA test substance and the inactivated test substance were administered to rats by gavage in single high doses. The animals were observed frequently on the day of dosing (Day 0) for mortality and

clinical signs of toxicity, and once daily thereafter for 21 days. An untreated control group was conducted concurrently. Tissue samples from treated rats were enumerated on days 0, 3, 7, 14, and 21. The test organism was not observed in plated blood, brain or liver. The urine from treated rats was completely clear of MPCA growth by 72 hours. The test organism cleared completely from the treated lungs, spleen, and kidney by Day 14. The mesenteric lymph nodes from treated rats did not achieve complete clearance, but declined to very low levels of growth found only in a single animal by Day 21. There were no signs of pharmacologic and/or toxicologic effects observed in any animal during the study, and no mortality occurred. The gross necropsy conducted at termination of the study revealed no internal abnormalities. The test substance, Howler™ Technical, was determined to be non-toxic to rats and demonstrate a pattern of clearance when administered by oral gavage in a single dose of 3.73 x 10^9 CFU/rat.

2. Acute Oral Toxicity (OCSPP 870.1100): The TGAI, Howler™ Technical (100% *Pseudomonas chlororaphis* strain AFS009), was not toxic following acute exposure by the oral route. An acute oral toxicity study was conducted on rats using the up-and-down procedure to determine the potential for Howler™ Technical to produce toxicity from a single oral dose (MRID No. 495680-03). An initial dose of 5,000 mg per kg body weight of the test substance was administered to a single female rat by gavage. This first rat survived and so two additional rats received a gavage dose of 5,000 mg/kg bw of the test material. All three animals survived, so no additional animals were tested. The rats were observed for mortality, clinical signs of toxicity and behavioral changes daily for 14 days. Body weights were recorded prior to exposure and again on Days 7 and 14. All animals survived test substance administration, gained body weight, and appeared active and healthy during the study. Necropsies were performed on all animals at terminal sacrifice. Under the study conditions, the acute oral LD50 of Howler™ Technical was greater than 5,000 mg/kg body weight in female rats (Toxicity Category IV).

3. Acute Dermal Toxicity (OCSPP 870.1200): The TGAI, Howler™ Technical (100% *Pseudomonas chlororaphis* strain AFS009) was not toxic following acute exposure by the dermal route. An acute dermal toxicity study was conducted on rats to determine the potential for Howler Technical to produce toxicity from a single topical application (MRID No. 495680-04). Five thousand milligrams (mg) of the test substance per kilogram (kg) of body weight was applied to the skin of 5 male and 5 female rats for 24 hours. The rats were observed for mortality, clinical signs of toxicity and behavioral changes daily for 14 days. Body weights were recorded prior to exposure and again on Days 7 and 14. Necropsies were performed on all animals at terminal sacrifice. Under the study conditions, the single dose acute dermal LD50 of Howler™ Technical was greater than 5,000 mg/kg body weight in male and female rats (Toxicity Category IV).

4. Acute Inhalation Toxicity Study in Rats (OCSPP 870.1300): An acute inhalation study demonstrates that the microbial pest control agent (MPCA), Howler™ Technical is not toxic by the inhalation route (MRID No. 495680-05). The TGAI, Howler™ Technical was not toxic to rats following an acute inhalation exposure. An acute inhalation toxicity study was conducted on rats to determine the

potential for Howler™ Technical to produce toxicity from a single 4-hour inhalation exposure. Ten healthy rats (5/sex) were exposed to the test atmosphere in a nose-only chamber for 4 hours. Chamber concentration and particle size distributions of the test atmosphere were determined periodically during the exposure period. The gravimetric chamber concentration was 5.04 mg/L and the average mass median aerodynamic diameter was estimated to be 2.39 µm. The animals were observed for mortality, clinical signs of toxicity, and behavioral changes daily for 14 days following exposure. Body weights were recorded prior to exposure and again on Days 1, 3, 7, and 14. Necropsies were performed on all animals at terminal sacrifice. Under the study conditions, the single dose acute inhalation LC50 of Howler Technical for a 4-hour exposure was greater than 5.05 mg/L (Toxicity Category IV).

5. Primary Eye Irritation (OCSPP 870.2400): The TGAI, Howler Technical (100% *Pseudomonas chlororaphis* strain AFS009), was not an eye irritant following a 24-hour ocular exposure to rabbits. One-tenth of a milliliter of Howler Technical was instilled into the right eyes of three healthy rabbits (MRID No. 495680-06). The left eyes remained untreated and served as controls. Ocular irritation was evaluated using the Draize scoring method. No ocular irritation was observed in any treated eye during the study, and the test substance was classified as non-irritating to the eye (Toxicity Category IV).

6. Primary Dermal Irritation (OCSPP 870.2500): The TGAI, Howler™ Technical (100% *Pseudomonas chlororaphis* strain AFS009), was not a dermal irritant following a 4-hour dermal exposure to rabbits. Five-tenths of a milliliter of Howler Technical was applied to the skin of three healthy rabbits and covered for four hours with a gauze pad and semi-occlusive tape (MRID No. 495680-07). Following exposure, dermal irritation was evaluated using the Draize scoring method. No dermal irritation was observed in any rabbit during the study, and the test substance was classified as non-irritating to the skin (Toxicity Category IV).

7. Hypersensitivity Incidents (OCSPP 885.3400): The registrant has noted that no incidents of hypersensitivity or any other adverse effects have occurred through the research, development or testing of the active ingredient and its related end-use product. Should any incidents occur, they will be reported per FIFRA Section 6(a)(2) (MRID No. 495680-16).

Literature searches have demonstrated that there are no reports of ecological or human health hazards caused by *Pseudomonas chlororaphis* strains. It does not produce recognized toxins, enzymes, or virulence factors normally associated with mammalian invasiveness or toxicity. *Pseudomonas chlororaphis* is an entomopathogenic fungus and a search of the literature demonstrates it is not reported to be pathogenic to humans. A search of the National Library of Medicine, PubMed, using the terms "*Pseudomonas chlororaphis*" AND "mammal" AND "pathogenicity" resulted in "No items found" (MRID No. 495680-16).

The results of toxicity testing show there is no risk to human health from the active ingredient. *Pseudomonas chlororaphis* strain AFS009 is not toxic, pathogenic, infective or irritating to mammals.

D. Aggregate Exposure

1. *Dietary exposure.*

i. *Food.* Dietary exposure from use of *Pseudomonas chlororaphis* strain AFS009, as proposed, is minimal. The intended use of *Pseudomonas chlororaphis* strain AFS009 is as a biological fungicide to growing plants in greenhouses, agricultural fields and home gardens for the purposes of disease control.

The results of toxicity testing indicate there is no risk to human health or the environment from *Pseudomonas chlororaphis* strain AFS009. There are no reports of ecological or human health hazards caused by this strain of *Pseudomonas chlororaphis*. It does not produce recognized toxins, enzymes, or virulence factors normally associated with mammalian invasiveness or toxicity. The absence of acute toxicity or pathogenicity in laboratory animals demonstrates the benign nature of this strain.

ii. *Drinking water.* Similarly, exposure to humans from residues of *Pseudomonas chlororaphis* strain AFS009 in consumed drinking water would be unlikely. Potential exposure to surface water would be negligible and exposure to drinking water (well or ground water) would be impossible to measure. *Pseudomonas chlororaphis* is a common bacterium found in soils (MRID No. 495680-16).

The intended use of *Pseudomonas chlororaphis* strain AFS009 is to growing plants in greenhouses, agricultural fields and home gardens for the purposes of disease control. The risk of the microorganism passing through the soil to ground water is minimal to unlikely. Additionally the fungus would not tolerate the conditions water is subjected to in a drinking water facility (including: chlorination, pH adjustments, high temperatures and/or anaerobic conditions).

The results of toxicity testing indicate there is no risk to human health or the environment from *Pseudomonas chlororaphis* strain AFS009. There are no reports of ecological or human health hazards caused by this microorganism. It does not produce recognized toxins, enzymes, or virulence factors normally associated with mammalian invasiveness or toxicity. The absence of acute toxicity or pathogenicity in laboratory animals demonstrates the benign nature of this strain.

2. *Non-dietary exposure.* The intended use of *Pseudomonas chlororaphis* strain AFS009 is to growing plants in greenhouses, agricultural fields and home gardens for the purposes of disease control. Personal Protective Equipment (PPE) mitigates the potential for exposure to applicators and handlers of the proposed products, when used in agricultural settings. *Pseudomonas chlororaphis* is a common bacterium found in soils (MRID No. 495680-16).

The results of toxicity testing indicate there is no risk to human health or the environment from *Pseudomonas chlororaphis* strain AFS009. There are no reports of ecological or human health hazards caused by this microorganism. It does not produce

recognized toxins, enzymes, or virulence factors normally associated with mammalian invasiveness or toxicity. The absence of acute toxicity or pathogenicity in laboratory animals demonstrates the benign nature of this strain. Non-dietary exposures would not be expected to pose any quantifiable risk due to a lack of residues of toxicological concern.

E. Cumulative Effects

It is not expected that, when used as proposed, *Pseudomonas chlororaphis* strain AFS009 would result in residues that are of toxicological concern. The intended use of *Pseudomonas chlororaphis* strain AFS009 is to growing plants in greenhouses, agricultural fields and home gardens for the purposes of disease control. The results of toxicity testing indicate there is no risk to human health or the environment from *Pseudomonas chlororaphis* strain AFS009. There are no reports of ecological or human health hazards caused by this microorganism. It does not produce recognized toxins, enzymes, or virulence factors normally associated with mammalian invasiveness or toxicity. The absence of acute toxicity or pathogenicity in laboratory animals demonstrates the benign nature of this strain.

F. Safety Determination

1. *U.S. population.* Acute toxicity studies have shown that *Pseudomonas chlororaphis* strain AFS009 is not toxic, pathogenic, infective or irritating to mammals. The intended use of *Pseudomonas chlororaphis* strain AFS009 is to growing plants in greenhouses, agricultural fields and home gardens for the purposes of disease control. The results of toxicity testing indicate there is no risk to human health or the environment from *Pseudomonas chlororaphis* strain AFS009. There are no reports of ecological or human health hazards caused by this microorganism. It does not produce recognized toxins, enzymes, or virulence factors normally associated with mammalian invasiveness or toxicity. The absence of acute toxicity or pathogenicity in laboratory animals demonstrates the benign nature of this strain. There is a reasonable certainty of no harm to the general US population from exposure to this active ingredient.

2. *Infants and children.* As mentioned above, it is not expected that, when used as proposed, *Pseudomonas chlororaphis* strain AFS009 would result in residues that are of toxicological concern. There is a reasonable certainty of no harm for infants and children from exposure to *Pseudomonas chlororaphis* strain AFS009 from the proposed uses.

G. Effects on the Immune and Endocrine Systems

To date there is no evidence to suggest that *Pseudomonas chlororaphis* strain AFS009 functions in a manner similar to any known hormone, or that it acts as an endocrine disrupter.

H. Existing Tolerances

There is no US EPA tolerance or tolerance exemption for *Pseudomonas chlororaphis* strain AFS009.

I. International Tolerances

A Codex Alimentarium Commission Maximum Residue Level (MRL) is not established for *Pseudomonas chlororaphis* strain AFS009.

Petition for an exemption from the requirement of a tolerance for residues of products containing the active ingredient "*Pseudomonas chlororaphis* strain AFS009" in and on all food commodities

Submitted by:

AFS009 Plant Protection, Inc. (EPA Co. No. 91197)
104 T.W. Alexander Drive, Building 18
Research Triangle Park, NC 27709

SECTION A Products and Proposed Use

Product Name: **Howler™ Technical (100% ai; TGAI) – EPA File Symbol 91197-R**
Howler™ (50% ai; EP) – EPA File Symbol 91197-G

Proposed Use Practice: Howler™ Technical is a 100% ai Technical Grade Active Ingredient (TGAI) of *Pseudomonas chlororaphis* strain AFS009 and is proposed for manufacturing use only, for further formulation into registered end-use products.

Howler™ is a 50% ai is formulated end-use product for use on growing plants and crops to control plant diseases including *Rhizoctonia, Pythium, Fusarium, Phytophthora* and *Botrytis.* Howler™ may be mixed with water and applied as a foliar spray, soil drench, in furrow spray, transplant spray or dip, cuttings or bare root dip, hydroponic or chemigation application in greenhouse, agricultural field, turf and ornamental and home and garden use sites.

SECTION B Product identity/chemistry

Active Ingredient: *Pseudomonas chlororaphis* strain AFS009 (CAS No. Not applicable).

Pseudomonas chlororaphis is a common bacterium identified primarily in the soil. *Pseudomonas chlororaphis* is a Gram-negative, rod-shaped bacteria with one or more flagella for motility. Information regarding the name, identity and composition has been submitted to EPA and can be found in MRID No. 495680-01.

Mode of Action: Like other *Pseudomonas chlororaphis* strains *Pseudomonas chlororaphis* strain AFS009 is a plant-colonizing bacteria which controls fungal diseases by several modes of action, including competition and production of a variety of metabolites which are inhibitory to the fungi. (MRID No. 495680-01).

Magnitude of residues and method to determine: An analytical method for residues is not applicable. It is expected that, when used as proposed, *Pseudomonas chlororaphis* strain AFS009, would not result in residues that are of toxicological concern.

SECTION C Toxicological Profile

Studies to evaluate the safety to mammals were conducted on the technical grade active ingredient (TGAI) and are summarized as follows:

1. Acute Oral Toxicity/Pathogenicity Study in Rats (OCSPP 885.3050): Howler™ Technical (100% *Pseudomonas chlororaphis* strain AFS009) was not toxic or pathogenic in rats following acute oral exposure to a concentrate of 3.73×10^9 (MRID No. 495680-02). The MPCA test substance and the inactivated test substance were administered to rats by gavage in single high doses. The animals were observed frequently on the day of dosing (Day 0) for mortality and clinical signs of toxicity, and once daily thereafter for 21days. An untreated control group was conducted concurrently. Tissue samples from treated rats were enumerated on days 0, 3, 7, 14, and 21. The test organism was not observed in plated blood, brain or liver. The urine from treated rats was completely clear of MPCA growth by 72 hours. The test organism cleared completely from the treated lungs, spleen, and kidney by Day 14. The mesenteric lymph nodes from treated rats did not achieve complete clearance, but declined to very low levels of growth found only in a single animal by Day 21. There were no signs of pharmacologic and/or toxicologic effects observed in any animal during the study, and no mortality occurred. The gross necropsy conducted at termination of the study revealed no internal abnormalities. The test substance, Howler™ Technical, was determined to be non-toxic to rats and demonstrate a pattern of clearance when administered by oral gavage in a single dose of 3.73×10^9 CFU/rat.

2. Acute Oral Toxicity (OCSPP 870.1100): The TGAI, Howler™ Technical (100% *Pseudomonas chlororaphis* strain AFS009), was not toxic following acute exposure by the oral route. An acute oral toxicity study was conducted on rats using the up-and-down procedure to determine the potential for Howler™ Technical to produce toxicity from a single oral dose (MRID No. 495680-03). An initial dose of 5,000 mg per kg body weight of the test substance was administered to a single female rat by gavage. This first rat survived and so two additional rats received a gavage dose of 5,000 mg/kg bw of the test material. All three animals survived, so no additional animals were tested. The rats were observed for mortality, clinical signs of toxicity and behavioral changes daily for 14 days. Body weights were recorded prior to exposure and again on Days 7 and 14. All animals survived test substance administration, gained body weight, and appeared active and healthy during the study. Necropsies were performed on all animals at terminal sacrifice. Under the study conditions, the acute oral LD50 of Howler™ Technical was greater than 5,000 mg/kg body weight in female rats (Toxicity Category IV).

3. Acute Dermal Toxicity (OCSPP 870.1200): The TGAI, Howler™ Technical (100% *Pseudomonas chlororaphis* strain AFS009) was not toxic following acute exposure by the dermal route. An acute dermal toxicity study was conducted on rats to determine the potential for Howler Technical to produce toxicity from a single topical application (MRID No. 495680-04). Five thousand milligrams (mg) of the test substance per kilogram (kg) of body weight was applied to the skin of 5 male and 5 female rats for 24 hours. The rats were observed for mortality, clinical signs of toxicity and behavioral changes daily for 14 days. Body weights were recorded prior to exposure and again on Days 7 and 14. Necropsies were performed on all animals at terminal sacrifice. Under the study conditions, the single

dose acute dermal LD50 of Howler™ Technical was greater than 5,000 mg/kg body weight in male and female rats (Toxicity Category IV).

4. Acute Inhalation Toxicity Study in Rats (OCSPP 870.1300): An acute inhalation study demonstrates that the microbial pest control agent (MPCA), Howler™ Technical is not toxic by the inhalation route (MRID No. 495680-05). The TGAI, Howler™ Technical was not toxic to rats following an acute inhalation exposure. An acute inhalation toxicity study was conducted on rats to determine the potential for Howler™ Technical to produce toxicity from a single 4-hour inhalation exposure. Ten healthy rats (5/sex) were exposed to the test atmosphere in a nose-only chamber for 4 hours. Chamber concentration and particle size distributions of the test atmosphere were determined periodically during the exposure period. The gravimetric chamber concentration was 5.04 mg/L and the average mass median aerodynamic diameter was estimated to be 2.39 µm. The animals were observed for mortality, clinical signs of toxicity, and behavioral changes daily for 14 days following exposure. Body weights were recorded prior to exposure and again on Days 1, 3, 7, and 14. Necropsies were performed on all animals at terminal sacrifice. Under the study conditions, the single dose acute inhalation LC50 of Howler Technical for a 4-hour exposure was greater than 5.05 mg/L (Toxicity Category IV).

5. Primary Eye Irritation (OCSPP 870.2400): The TGAI, Howler Technical (100% *Pseudomonas chlororaphis* strain AFS009), was not an eye irritant following a 24-hour ocular exposure to rabbits. One-tenth of a milliliter of Howler Technical was instilled into the right eyes of three healthy rabbits (MRID No. 495680-06). The left eyes remained untreated and served as controls. Ocular irritation was evaluated using the Draize scoring method. No ocular irritation was observed in any treated eye during the study, and the test substance was classified as non-irritating to the eye (Toxicity Category IV).

6. Primary Dermal Irritation (OCSPP 870.2500): The TGAI, Howler™ Technical (100% *Pseudomonas chlororaphis* strain AFS009), was not a dermal irritant following a 4-hour dermal exposure to rabbits. Five-tenths of a milliliter of Howler Technical was applied to the skin of three healthy rabbits and covered for four hours with a gauze pad and semi-occlusive tape (MRID No. 495680-07). Following exposure, dermal irritation was evaluated using the Draize scoring method. No dermal irritation was observed in any rabbit during the study, and the test substance was classified as non-irritating to the skin (Toxicity Category IV).

7. Hypersensitivity Incidents (OCSPP 885.3400): The registrant has noted that no incidents of hypersensitivity or any other adverse effects have occurred through the research, development or testing of the active ingredient and its related end-use product. Should any incidents occur, they will be reported per FIFRA Section 6(a)(2)(MRID No. 495680-16).

Literature searches have demonstrated that there are no reports of ecological or human health hazards caused by *Pseudomonas chlororaphis* strains. It does not produce recognized toxins, enzymes, or virulence factors normally associated with mammalian invasiveness or toxicity. *Pseudomonas chlororaphis* is an entomopathogenic fungus and a search of the literature demonstrates it is not reported to be pathogenic to humans. A search of the National Library of Medicine, PubMed, using the terms "*Pseudomonas chlororaphis*" AND "mammal" AND "pathogenicity" resulted in "No items found" (MRID No. 495680-16).

The results of toxicity testing show there is no risk to human health from the active ingredient. *Pseudomonas chlororaphis* strain AFS009 is not toxic, pathogenic, infective or irritating to mammals.

SECTION D Aggregate Exposure

1) Dietary Exposure:

Dietary exposure from use of *Pseudomonas chlororaphis* strain AFS009, as proposed, is minimal. The intended use of *Pseudomonas chlororaphis* strain AFS009 is as a biological fungicide to growing plants in greenhouses, agricultural fields and home gardens for the purposes of disease control.

The results of toxicity testing indicate there is no risk to human health or the environment from *Pseudomonas chlororaphis* strain AFS009. There are no reports of ecological or human health hazards caused by this strain of *Pseudomonas chlororaphis*. It does not produce recognized toxins, enzymes, or virulence factors normally associated with mammalian invasiveness or toxicity. The absence of acute toxicity or pathogenicity in laboratory animals demonstrates the benign nature of this strain.

2) Drinking Water Exposure:

Similarly, exposure to humans from residues of *Pseudomonas chlororaphis* strain AFS009 in consumed drinking water would be unlikely. Potential exposure to surface water would be negligible and exposure to drinking water (well or ground water) would be impossible to measure. *Pseudomonas chlororaphis* is a common bacterium found in soils (MRID No. 495680-16).

The intended use of *Pseudomonas chlororaphis* strain AFS009 is to growing plants in greenhouses, agricultural fields and home gardens for the purposes of disease control. The risk of the microorganism passing through the soil to ground water is minimal to unlikely. Additionally the fungus would not tolerate the conditions water is subjected to in a drinking water facility (including: chlorination, pH adjustments, high temperatures and/or anaerobic conditions).

The results of toxicity testing indicate there is no risk to human health or the environment from *Pseudomonas chlororaphis* strain AFS009. There are no reports of ecological or human health hazards caused by this microorganism. It does not produce recognized toxins, enzymes, or virulence factors normally associated with mammalian invasiveness or toxicity. The absence of acute toxicity or pathogenicity in laboratory animals demonstrates the benign nature of this strain.

3) Non-Dietary Exposure:

The intended use of *Pseudomonas chlororaphis* strain AFS009 is to growing plants in greenhouses, agricultural fields and home gardens for the purposes of disease control. Personal Protective Equipment (PPE) mitigates the potential for exposure to applicators and handlers of the proposed products, when used in agricultural settings. *Pseudomonas chlororaphis* is a common bacterium found in soils (MRID No. 495680-16).

The results of toxicity testing indicate there is no risk to human health or the environment from *Pseudomonas chlororaphis* strain AFS009. There are no reports of ecological or human health hazards caused by this microorganism. It does not produce recognized toxins, enzymes, or virulence factors normally associated with mammalian invasiveness or toxicity. The absence of acute toxicity or pathogenicity in laboratory animals demonstrates the benign nature of this strain. Non-dietary exposures would not be expected to pose any quantifiable risk due to a lack of residues of toxicological concern.

SECTION E Cumulative Effects

It is not expected that, when used as proposed, *Pseudomonas chlororaphis* strain AFS009 would result in residues that are of toxicological concern. The intended use of *Pseudomonas chlororaphis* strain AFS009 is to growing plants in greenhouses, agricultural fields and home gardens for the purposes of disease control. The results of toxicity testing indicate there is no risk to human health or the environment from *Pseudomonas chlororaphis* strain AFS009. There are no reports of ecological or human health hazards caused by this microorganism. It does not produce recognized toxins, enzymes, or virulence factors normally associated with mammalian invasiveness or toxicity. The absence of acute toxicity or pathogenicity in laboratory animals demonstrates the benign nature of this strain.

SECTION F Safety Determination

1) General US Population:

Acute toxicity studies have shown that *Pseudomonas chlororaphis* strain AFS009 is not toxic, pathogenic, infective or irritating to mammals. The intended use of *Pseudomonas chlororaphis* strain AFS009 is to growing plants in greenhouses, agricultural fields and home gardens for the purposes of disease control. The results of toxicity testing indicate there is no risk to human health or the environment from *Pseudomonas chlororaphis* strain AFS009. There are no reports of ecological or human health hazards caused by this microorganism. It does not produce recognized toxins, enzymes, or virulence factors normally associated with mammalian invasiveness or toxicity. The absence of acute toxicity or pathogenicity in laboratory animals demonstrates the benign nature of this strain. There is a reasonable certainty of no harm to the general US population from exposure to this active ingredient.

2) Infants and Children:

As mentioned above, it is not expected that, when used as proposed, *Pseudomonas chlororaphis* AFS009 would result in residues that are of toxicological concern. There is a reasonable certainty of no harm for infants and children from exposure to *Pseudomonas chlororaphis* strain AFS009 from the proposed uses.

SECTION G – Effects on Immune and Endocrine Systems

To date there is no evidence to suggest that *Pseudomonas chlororaphis* strain AFS009 functions in a manner similar to any known hormone, or thatit acts as an endocrine disrupter.

SECTION H – Existing Tolerances

There is no US EPA tolerance or tolerance exemption for *Pseudomonas chlororaphis* strain AFS009.

SECTION I – International Tolerances

A Codex Alimentarium Commission Maximum Residue Level (MRL) is not established for *Pseudomonas chlororaphis* strain AFS009.

Cerrelli, Susanne

From: Wakefield, Benjamin J.
Sent: Friday, October 14, 2016 6:27 PM
To: Cerrelli, Susanne
Cc: Kausch, Jeannine
Subject: RE: Pseudomonas chlororaphis subsp. aurantiaca strain AFS009 dockets and question about removing sub species from the Active ingredient name
Attachments: RE: Notice of Filing Question

Follow Up Flag: Follow up
Flag Status: Flagged

Confidential - Privileged - Deliberative - Do Not Disclose

Susanne,

[redacted]

- Ben

Benjamin J. Wakefield

U.S. Environmental Protection Agency
Office of General Counsel, Pesticides & Toxic Substances Law Office
1200 Pennsylvania Ave., N.W., Mail Code 2333A
Washington, D.C. 20460
Tel: 202-564-3186
Fax: 202-564-5531
wakefield.benjamin@epa.gov

From: Cerrelli, Susanne
Sent: Thursday, October 06, 2016 4:05 PM
To: Wakefield, Benjamin J. <wakefield.benjamin@epa.gov>
Cc: Kausch, Jeannine <Kausch.Jeannine@epa.gov>
Subject: Pseudomonas chlororaphis subsp. aurantiaca strain AFS009 dockets and question about removing sub species from the Active ingredient name

Ben-

[redacted]

https://www.regulations.gov/document?D=EPA-HQ-OPP-2016-0284-0003
Anonymous public comment

Comment in NOF:

View document:

i oppose approval of the plant protection company profiting from pseudomonas chloroaphis. aphis is a division of wildife services using general tax dollars gouged from general american taxpayers for the use of this divisino which does research but also is in the business of gaining money and revenue from killing wildlife. this agency killed over 3 billions animals last year and every year. they are harmful, devil, evil people who do such wholesale killing. i also note that they do not seem very effeiciant, effective, or innotative or interested in safety in theri research group. i am very muchg opposed to this chemical added to our food. oppose this approval.

-Regards,

Susanne Cerrelli
Regulatory Action Leader
Biopesticides Pollution Prevention Division
703-308-8077

SENDER: COMPLETE THIS SECTION

- Complete items 1, 2, and 3. Also complete item 4 if Restricted Delivery is desired.
- Print your name and address on the reverse so that we can return the card to you.
- Attach this card to the back of the mailpiece, or on the front if space permits.

1. Article Addressed to:

Amy Plato Roberts, Senior Regulatory Consultant
Technology Sciences Group Inc. (TSG)
712 Fifth St. Suite A
Davis, CA 95616

COMPLETE THIS SECTION ON DELIVERY

A. Signature
X [signature] ☑ Agent ☐ Addressee

B. Received by (Printed Name) Vicki Quinn
C. Date of Delivery 1/25/16

D. Is delivery address different from item 1? ☐ Yes
If YES, enter delivery address below: ☐ No

3. Service Type
☑ Certified Mail ☐ Express Mail
☐ Registered ☑ Return Receipt for Merchandise
☐ Insured Mail ☐ C.O.D.

4. Restricted Delivery? (Extra Fee) ☐ Yes

2. Article Number (Transfer from service label) 7008 3230 0000 9474 1835

PS Form 3811, February 2004 Domestic Return Receipt 102595-02-M-1540

Petition

5F 8410

UNITED STATES POSTAL SERVICE

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• Sender: Please print your name, address, and ZIP+4 in this box •

ATTN: Susanne Cerrelli (7511P)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460

FCL20242081

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

January 19, 2016

CONTAINS CONFIDENTIAL BUSINESS INFORMATION

BY CERTIFIED MAIL, RETURN RECEIPT REQUESTED

OPP Decision Numbers: D510002, D510004, D510005, and D510007
EPA File Symbols: 91197-R, 91197-E, 91197-G
Pesticide Petition Number: 5F8410
Product Names: Howler™ Technical, Howler™ T&O, and Howler™
EPA Receipt Date: October 2, 2015
EPA Company Number: 91197
Company Name: AFS009 Plant Protection, Inc.

Amy Plato Roberts, Senior Regulatory Consultant
Senior Regulatory Consultant for AFS009 Plant Protection, Inc.
Technology Sciences Group Inc. (TSG)
712 Fifth St. Suite A
Davis, CA 95616

Dear Ms. Roberts:

The U.S. Environmental Protection Agency (Agency or EPA) has completed its preliminary technical screening of your applications pursuant to Section 33(f)(4)(B)(i)(II) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended by the Pesticide Registration Improvement Extension Act (PRIA 3). The EPA has determined that your applications have not passed the preliminary technical screening and therefore are subject to rejection if the applications are not corrected.

Specifically, you must provide the data and/or information described below:

1. The data to support the product identity (OCSPP Guideline 885.1100) for Howler™ Technical (MRID 495680-01) is incomplete. This is a data deficiency, and must be corrected. Specifically, you must do the following:

    a. MRID 495680-01 describes FAME, API 20 NE, and other phenotype data that are available as part of the product identity description. However, these data are not included in MRID 495680-01. You must provide these data for review. Additionally, recent reclassification of several Pseudomonads and pertinent definitive phenotypic and genetic

tests are listed in Peix et al. (2007)[1]. In providing the additional identity data, you must also compare published definitive identification tests to your data to confirm identity.

b. It is unclear whether strain AFS009 is an isolate of strain MA 342 or is of unique origin. You must clarify this issue, and if AFS009 is of unique origin, you must provide information on its origin and describe any previous regulatory history.

2. MRID 495680-13 supporting the Analysis of Samples data requirement (OCSPP Guideline 885.1400) contains an illegible page (page 87 of 92), and this data volume thus cannot be reviewed. You must provide a legible and complete copy of this page. You may submit to BPPD the replacement page, but you must also ensure that Document Processing receives the corrected page so that MRID 495680-13 is correct and readable for our records.

3. The data to support the Nontarget Insect Testing data requirement (OCSPP Guideline 885.4340) is incomplete. The following data deficiencies were noted for the parasitic wasp study (MRID 495680-13), and must be addressed:

   a. There is a discrepancy between mortality percentages reported on page 14 and in Table 3 on pages 17 and 18 of the study report. The conclusion on page 14 states that mortality was 28.4% and 15.5% for the inactive test substance and the active test substance group, respectively. However, Table 3 reports different percentages (59.5% and 18.7% for inactive and active test substance, respectively). You must explain or correct this discrepancy, and provide exact calculations to show how these percentages were derived.

   b. Insufficient information is provided to confirm the dosing calculation. You must specify how many grams of test substance were used for the dosing solution to result in the concentration intended.

   c. It is unclear what end use product application rate corresponds to the exposure level of the test insects in this study. You must clarify this issue, and explain specifically how you calculated the dose from this application rate, particularly since the application rate is expressed in ounces per acre and the exposure level in the study is expressed as a concentration (cfu/mL).

In order for the review of your pesticide products to continue, you will need to correct your applications to address the items listed above within 10 business days of the date you received this letter. The EPA must receive your corrections by the 10th business day. The EPA recommends sending your complete set of corrections by email to the contact listed below to ensure they are received in a timely manner. If studies or confidential business information are being submitted by mail, a complete courtesy copy received by email by the deadline will be considered timely. If you cannot correct the applications or do not respond within 10 business days, your applications will be rejected. At this time, you could also choose to withdraw your applications.

[1] Peix, A. (et al.). 2007. Reclassification of *Pseudomonas aurantiaca* as a synonym of *Pseudomonas chlororaphis* and proposal of three subspecies, *P. chlororaphis* subsp. *chlororaphis* subsp. nov., *P. chlororaphis* subsp. *aureofaciens* subsp. nov., comb. nov. and *P. chlororaphis* subsp. *aurantiaca* subsp. nov., comb. nov. International Journal of Systematic and Evolutionary Microbiology 57:1286-1290

In addition to the deficiencies listed above, the preliminary technical screening identified the following shortcomings. Addressing these shortcomings now will improve the likelihood your applications can be granted as requested and in an efficient manner.

4. The results of your five batch analysis do not support potency claims of 5 x 10^{11} CFU/g (see pages 64-74 of 92 of MRID 495680-01) on the label and Confidential Statement of Formula (CSF) for Howler™ Technical. Specifically, they indicate potency of 1.94 x 10^{10} CFU/g or only slightly higher. To support the Certification of Limits data requirement (OCSPP Guideline 885.1500), you must correct the statement of potency on the label and CSF for this product to more accurately reflect its potency.

5. The storage stability data (OCSPP Guideline 830.6317) for EPA file symbols 91197-E and 91197-G will be inadequate to support a product without a one month expiration statement. If you do not supply additional storage stability information indicating sufficient viability for a longer period, you will be required to place an expiration date on the package indicating that it expires one month from production.

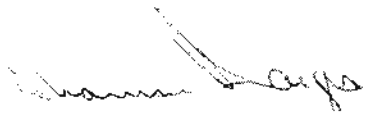
6. The respirator description in the Personal Protective Equipment (PPE) section of the End-use product labels must be updated to state:

   "A NIOSH approved particulate respirator with any N, R, or P filter with NIOSH approval number prefix TC-84A; or a NIOSH approved powered air purifying respirator with an HE filter with NIOSH approval number prefix TC-21C. (Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.)"

   Please note this updated text is required to ensure the mask fits appropriately to ensure safety to the handler. We request that you include this respirator text revision when you submit revised labels to facilitate the risk assessments of the applicant's products.

If you have questions concerning this letter, please contact Susanne Cerrelli of my team by telephone at (703) 308-8077 or via email at cerrelli.susanne@epa.gov.

Sincerely,



Shannon Borges, Team Leader
Microbial Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)
Office of Pesticide Programs

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 10-2-15

Experts In-Processing Signature: B.B. Date 10-13-15 Fee Paid: Yes ✓

Division management contacted on issues No _____ Yes _____ Date _____

EPA Reg. Number: 5F8410	EPA Receipt Date: 10-2-15

	Items for Review	Yes	No	N/A*
1	**Application Form** (EPA Form 8570-1) signed & complete including package type			X
2	**Confidential Statement of Formula** all boxes completed, form signed, and dated (EPA Form 8570-4)			X
	a) All inerts, including fragrances, approved for the proposed uses (see Footnote A) — yes / no			
	No inerts to review			
3	**Certification with Respect to Citation of Data** (EPA Form 8570-34) completed and signed (N/A if 100% repack)			X
	Certificate and data matrix consistent			
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B) — yes / no			
	If applicable, is there a letter of Authorization for exclusive use only.			
4	**Formulator's Exemption Statement** (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)			X
5	**Data Matrix** (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)			X
	a) Selective Method (Fee category experts use) — yes / no			
	b) Cite-All (Fee category experts use)			
	c) Applicant owns all data (Fee category experts use)			
6	**5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)**			
7	**Is the data package consistent with PR Notice 86-5**			X
8	**Notice of Filing included with petitions**	X		

9	**If applicable for conventional applications, <u>reduced risk rationale</u>**			X
10	**<u>Required Data</u> and/or data waivers. See Footnote C.**			
	a) List study (or studies) not included with application			

Comments:

* Documentation: (Pass) / Fail
  - required forms are complete
  - related to Reg # 91197-G
* Inerts: (Pass) / Fail
  - no inerts to review. No CSF
* PRN 11-3: (Pass) / Fail
  - No studies submitted
* Overall Status: (Pass) / Fail

SW 10-26-15

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the inert Web site and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient.** Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch.

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or

3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or

2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

October 13, 2015

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-510007
EPA File Symbol or Registration Number: 5F8410
Description: Tolerance Exemption Petition
EPA Receipt Date: 02-Oct-2015
EPA Company Number: 91197
Company Name: AGBIOME INC.

MS. AMY PLATO ROBERTS
TECHNOLOGY SCIENCES GROUP, INC.
AGBIOME INC.
1150 18TH ST. N.W.
WASHINGTON, DC 20036-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your toleance petition. If you submitted data with this petition, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: B590

NEW AI;FOOD USE;MICROBIAL/BIOCHEMICAL;PETITION TO ESTABLISH A TOLERANCE EXEMPTION;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-1259.

Sincerely,

Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service {9753264~

This package includes the following

- ◉ New Registration
- ○ Amendment

☐ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ___

for Division

- ○ AD
- ◉ BPPD
- ○ RD

Risk Mgr. 92

Receipt No. S- 975326

EPA File Symbol/Reg. No. 5F8410

Pin-Punch Date: 10/2/2015

☐ This item is NOT subject to FFS action.

Action Code:

Requested: B590.0

Granted: B 590.0

Amount Due: $ _____

Parent/Child Decisions:

☐ Inert Cleared for Intended Use ☐ Uncleared Inert in Product

Reviewer:_____ Date:_____

Remarks:

See Attached

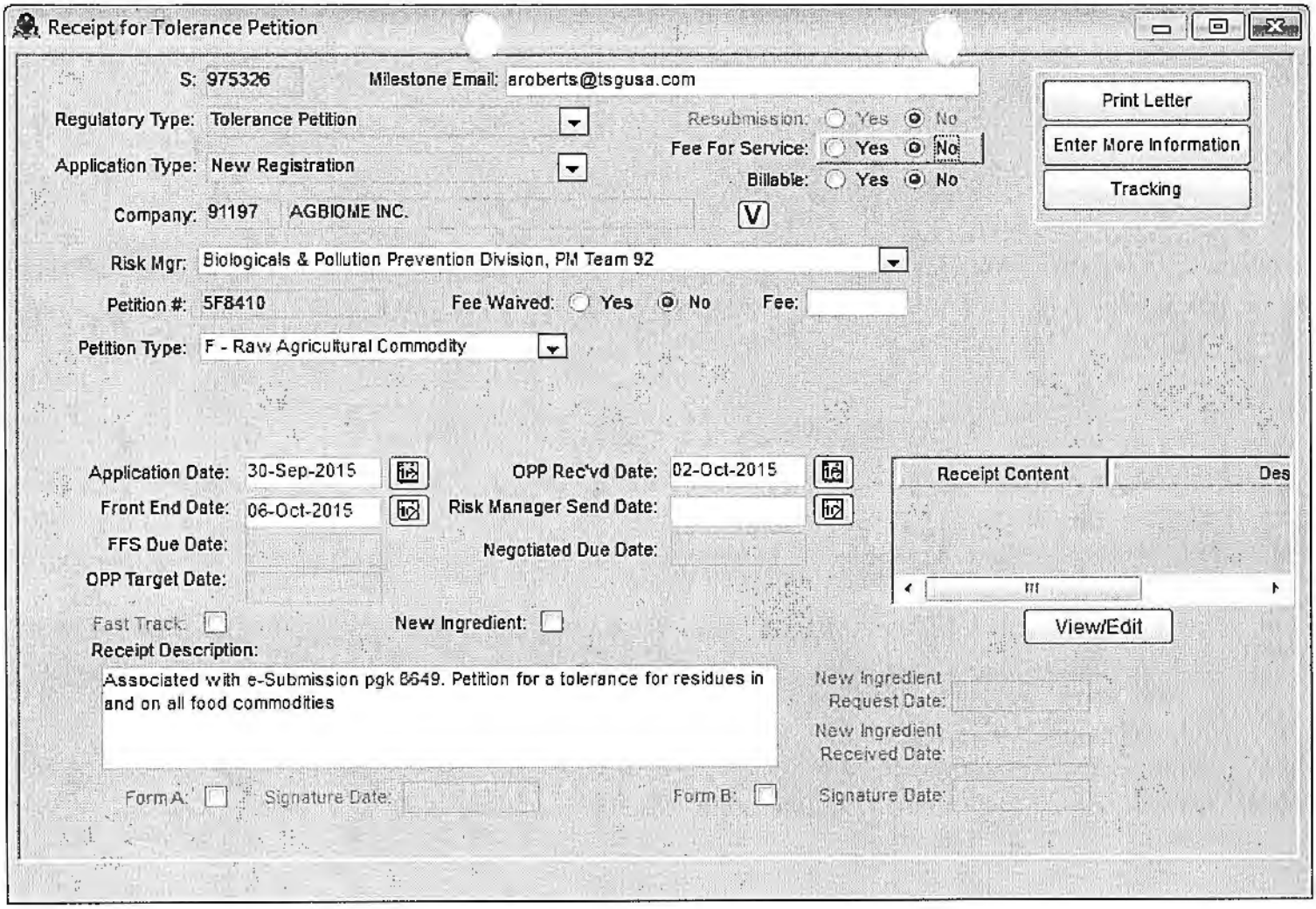
PRISM Documentum

ISB In Processing : 5F8410 S975326 2015-10-06
Description: 5F8410 S975326 2015-10-06
From: Doc Admin
Received: 10/6/2015 4:29 PM
WorkFlow Instructions:

975326 : Comments

Comment	Author	Date
PRIA REQUESTED ACTION CODE = B590.0 GRANTED ACTION CODE = B590.0 Amount due = included Parent action = 91197-G Child action = 5F8410 Other Remarks = This is a new a.i. Please note that 91197-R and 91197-E were submitted as B600 (non-food) at the same time that 91197-G and 5F8410 were submitted as B590 (food use with petition). The company requested this so that they could get non-food uses registered sooner. Please let me know if you have questions (Shannon - 703- 305-7175).	Borges, Shannon	10/6/2015 4:29 PM


IR-4 related submission (Y or N)? N
Similarity Clinic Review Required (Y/N)? N
Add


Receipt for Tolerance Petition
S: 975326
Milestone Email: aroberts@tsgusa.com
Regulatory Type: Tolerance Petition
Application Type: New Registration
Company: 91197 AGBIOME INC.
Resubmission: Yes No
Fee For Service: Yes No
Billable: Yes No
Print Letter
Enter More Information
Tracking
Risk Mgr: Biologicals & Pollution Prevention Division, PM Team 92
Petition #: 5F8410
Fee Waived: Yes No
Fee:
Petition Type: F - Raw Agricultural Commodity
Application Date: 30-Sep-2015
Front End Date: 06-Oct-2015
FFS Due Date:
OPP Target Date:
OPP Rec'vd Date: 02-Oct-2015
Risk Manager Send Date:
Negotiated Due Date:
Receipt Content
Des
Fast Track:
New Ingredient:
View/Edit
Receipt Description:
Associated with e-Submission pgk 8649. Petition for a tolerance for residues in and on all food commodities
New Ingredient Request Date:
New Ingredient Received Date:
Form A:
Signature Date:
Form B:
Signature Date:

Technology Sciences Group Inc.

1150 18th Street NW, Suite 1000
Washington, DC 20036
Direct dial: (208) 788-0217
Fax: (202) 872-0745
E-Mail: aroberts@tsgusa.com

Amy Plato Roberts
Senior Regulatory Consultant

ShaRon Carlisle, Associated Branch, Microbial Pesticides Branch
Biopesticides and Pollution Prevention Division (7511P)
Office of Pesticide Programs, EPA
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

September 30, 2015

RE: Petition to establish an exemption from the requirement of a tolerance for residues of products containing the active ingredient "*Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009" in and on all food commodities

Dear Ms. Carlisle:

With this letter Technology Sciences Group Inc., on behalf of AFS009 Plant Protection, Inc. (91197), hereby submits a petition to establish an exemption from the requirement of a tolerance for residues of products containing the microbial active ingredient "***Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009**" in and on all food commodities, in accordance with 40 CFR Part 180 and pursuant to Section 408(d)(1) of the Federal Food, Drug and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

In support of this petition, attached you will find the following information:

A. Product name and proposed use practice;
B. Product identity/chemistry, including identity of the pesticide and corresponding residues, magnitude of residues and method to determine;
C. Mammalian toxicological profile;
D. Aggregate exposure, including information on dietary exposure, food, drinking water exposure and non-dietary exposure;
E. Cumulative effects;
F. Safety determination, including information on the U.S. general population, and infants and children;
G. Effects on the immune and endocrine systems;
H. Existing tolerances;
I. International Tolerances.

Data supporting this petition has been concurrently submitted for new active ingredient registration applications, as follows:

- *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009 Technical (91197-R);
- Howler™ T&O (91197-G).

The petitioner agrees that the enclosed information may be published as part of the notice of filing of the petition, to be published under Section 408(d)(1), and as proposed for final regulation.

An draft electronic Notice of Filing is also included in this submission for your use. Should you have any questions or comments on this petition please contact me directly.

Sincerely,

Amy Plato Roberts
Regulatory Consultant for AFS009 Plant Protection, Inc.
Direct dial (208) 788-0217; aroberts@tsgusa.com

Amy Roberts

From: Borges, Shannon <Borges.Shannon@epa.gov>
Sent: Friday, June 13, 2014 7:31 AM
To: Amy Roberts; Nesci, Kimberly; Mendelsohn, Mike
Subject: RE: Question on a new microbial ai - going food and non-food simultaneously

Hi Amy,

Sorry for the delay in our reply! Yes, you can submit products under food use and non-food use PRIA codes simultaneously. This would be similar to a situation where someone submits and application for another product while the related new a.i. application is still pending.

Regards,
Shannon

From: Amy Roberts [mailto:ARoberts@TSGUSA.COM]
Sent: Tuesday, June 03, 2014 4:27 PM
To: Nesci, Kimberly; Mendelsohn, Mike; Borges, Shannon
Subject: Question on a new microbial ai - going food and non-food simultaneously
Importance: High

Hi Kimberly, Mike and Shannon:

Question on a new microbial ai.

Is it possible to submit as food use and non-food use simultaneously? So submit it as two PRIA action codes – a B590 (with a food use EP and tolerance exemption petition) and a B600 (with a non-food use EP) – and pay two fees and have the applications track simultaneously. Maybe have the TGAI package as part of the B600, and just the food use EP and tolerance exemption under the B590.

The purpose of doing this would be to have, assuming there are no issues and PRIA renegotiations, a non-food use EP out 4 months before a food use EP to hit turf and ornamental markets. I have never heard of this being done, but don't see that it is prohibited under PRIA.

Thoughts?

Amy Plato Roberts | Senior Regulatory Consultant
Technology Sciences Group Inc. (TSG)
PO Box 990 | Hailey, ID 83333 USA
NEW Tel: 208.788.0217 | Fax: 530.757.1299 | Email: aroberts@TSGUSA.com | Skype: ARobertsTSG
Visit us at www.TSGUSA.com

e-mail in error, notify the sender immediately and permanently delete the e-mail, any attachments, and all copies thereof from any drives or storage media and destroy any printouts of the e-mail or attachments

EPA BIOPESTICIDES AND POLLUTION PREVENTION DIVISION COMPANY NOTICE OF FILING FOR PESTICIDE PETITIONS PUBLISHED IN THE FEDERAL REGISTER

EPA Biopesticides and Pollution Prevention Division contact: ShaRon Carlisle; (703) 308-6427

INSTRUCTIONS: **Please utilize this outline in preparing the pesticide petition. In cases where the outline element does not apply, please insert "NA-Remove" and maintain the outline. Please do not change the margins, font, or format in your pesticide petition. Simply replace the instructions that appear in green, i.e., "[insert company name]," with the information specific to your action.**

SUBMISSION: **E-mail the completed template to: hollis.linda@epa.gov.**

TEMPLATE:

AFS009 Plant Protection, Inc. (EPA Co. No. 91197)

[Insert petition number]

EPA has received a pesticide petition **([insert petition number])** from AFS009 Plant Protection, Inc. (EPA Co. No. 91197), 104 T.W. Alexander Drive, Building 18, Research Triangle Park, NC 27709 proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish an exemption from the requirement of a tolerance for microbial pesticide *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009.

Pursuant to section 408(d)(2)(A)(i) of FFDCA, as amended, AFS009 Plant Protection, Inc. (EPA Co. No. 91197) has submitted the following summary of information, data, and arguments in support of their pesticide petition. This summary was prepared by AFS009 Plant Protection, Inc. (EPA Co. No. 91197) and EPA has not fully evaluated the merits of the pesticide petition. The summary may have been edited by EPA if the terminology used was unclear, the summary contained extraneous material, or the summary unintentionally made the reader conclude that the findings reflected EPA's position and not the position of the petitioner.

I. AFS009 Plant Protection, Inc. (EPA Co. No. 91197) **Petition Summary**

[Insert petition number]

A. Product Name and Proposed Use Practices

Product Name: **Howler™ Technical (100% ai; TGAI) – EPA File Symbol 91197-R**
Howler™ (50% ai; EP) – EPA File Symbol 91197-G

Proposed Use Practice: Howler™ Technical is a 100% ai Technical Grade Active Ingredient (TGAI) of *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009 and is proposed for manufacturing use only, for further formulation into registered end-use products.

Howler™ is a 50% ai is formulated end-use product for use on growing plants and crops to control plant diseases including *Rhizoctonia, Pythium, Fusarium, Phytophthora* and *Botrytis*. Howler™ may be mixed with water and applied as a foliar spray, soil drench, in furrow spray, transplant spray or dip, cuttings or bare root dip, hydroponic or chemigation application in greenhouse, agricultural field, turf and ornamental and home and garden use sites.

B. Product Identity/Chemistry

1. *Identity of the pesticide and corresponding residues.* *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009 (CAS No. Not applicable).

Pseudomonas chlororaphis is a common bacterium identified primarily in the soil. *Pseudomonas chlororaphis* subsp. *aurantiaca* is a Gram-negative, rod-shaped bacteria with one or more flagella for motility. Information regarding the name, identity and composition has been submitted to EPA and can be found in MRID No. 495680-01.

Like other *Pseudomonas chlororaphis* strains *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009 is a plant-colonizing bacteria which controls fungal diseases by several modes of action, including competition and production of a variety of metabolites which are inhibitory to the fungi. (MRID No. 495680-01).

2. *Magnitude of residues at the time of harvest and method used to determine the residue.* **NA-Remove**

3. *A statement of why an analytical method of detecting and measuring the levels of the pesticide residue are not needed.* An analytical method for residues is not applicable. It is expected that, when used as proposed, *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009, would not result in residues that are of toxicological concern.

C. Mammalian Toxicological Profile

Studies to evaluate the safety to mammals were conducted on the technical grade active ingredient (TGAI) and are summarized as follows:

1. Acute Oral Toxicity/Pathogenicity Study in Rats (OCSPP 885.3050): Howler™ Technical (100% *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009) was not toxic or pathogenic in rats following acute oral exposure to a concentrate of 3.73×10^9 (MRID No. 495680-02). The MPCA test substance and the inactivated test substance were administered to rats by gavage in single high

doses. The animals were observed frequently on the day of dosing (Day 0) for mortality and clinical signs of toxicity, and once daily thereafter for 21 days. An untreated control group was conducted concurrently. Tissue samples from treated rats were enumerated on days 0, 3, 7, 14, and 21. The test organism was not observed in plated blood, brain or liver. The urine from treated rats was completely clear of MPCA growth by 72 hours. The test organism cleared completely from the treated lungs, spleen, and kidney by Day 14. The mesenteric lymph nodes from treated rats did not achieve complete clearance, but declined to very low levels of growth found only in a single animal by Day 21. There were no signs of pharmacologic and/or toxicologic effects observed in any animal during the study, and no mortality occurred. The gross necropsy conducted at termination of the study revealed no internal abnormalities. The test substance, Howler™ Technical, was determined to be non-toxic to rats and demonstrate a pattern of clearance when administered by oral gavage in a single dose of 3.73 x 10^9 CFU/rat.

2. Acute Oral Toxicity (OCSPP 870.1100): The TGAI, Howler™ Technical (100% *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009), was not toxic following acute exposure by the oral route. An acute oral toxicity study was conducted on rats using the up-and-down procedure to determine the potential for Howler™ Technical to produce toxicity from a single oral dose (MRID No. 495680-03). An initial dose of 5,000 mg per kg body weight of the test substance was administered to a single female rat by gavage. This first rat survived and so two additional rats received a gavage dose of 5,000 mg/kg bw of the test material. All three animals survived, so no additional animals were tested. The rats were observed for mortality, clinical signs of toxicity and behavioral changes daily for 14 days. Body weights were recorded prior to exposure and again on Days 7 and 14. All animals survived test substance administration, gained body weight, and appeared active and healthy during the study. Necropsies were performed on all animals at terminal sacrifice. Under the study conditions, the acute oral LD50 of Howler™ Technical was greater than 5,000 mg/kg body weight in female rats (Toxicity Category IV).

3. Acute Dermal Toxicity (OCSPP 870.1200): The TGAI, Howler™ Technical (100% *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009) was not toxic following acute exposure by the dermal route. An acute dermal toxicity study was conducted on rats to determine the potential for Howler Technical to produce toxicity from a single topical application (MRID No. 495680-04). Five thousand milligrams (mg) of the test substance per kilogram (kg) of body weight was applied to the skin of 5 male and 5 female rats for 24 hours. The rats were observed for mortality, clinical signs of toxicity and behavioral changes daily for 14 days. Body weights were recorded prior to exposure and again on Days 7 and 14. Necropsies were performed on all animals at terminal sacrifice. Under the study conditions, the single dose acute dermal LD50 of Howler™ Technical was greater than 5,000 mg/kg body weight in male and female rats (Toxicity Category IV).

4. Acute Inhalation Toxicity Study in Rats (OCSPP 870.1300): An acute inhalation study demonstrates that the microbial pest control agent (MPCA), Howler™ Technical is not toxic by the inhalation route (MRID No. 495680-05). The TGAI, Howler™ Technical was not toxic to rats following an acute inhalation exposure.

An acute inhalation toxicity study was conducted on rats to determine the potential for Howler™ Technical to produce toxicity from a single 4-hour inhalation exposure. Ten healthy rats (5/sex) were exposed to the test atmosphere in a nose-only chamber for 4 hours. Chamber concentration and particle size distributions of the test atmosphere were determined periodically during the exposure period. The gravimetric chamber concentration was 5.04 mg/L and the average mass median aerodynamic diameter was estimated to be 2.39 µm. The animals were observed for mortality, clinical signs of toxicity, and behavioral changes daily for 14 days following exposure. Body weights were recorded prior to exposure and again on Days 1, 3, 7, and 14. Necropsies were performed on all animals at terminal sacrifice. Under the study conditions, the single dose acute inhalation LC50 of Howler Technical for a 4-hour exposure was greater than 5.05 mg/L (Toxicity Category IV).

5. Primary Eye Irritation (OCSPP 870.2400): The TGAI, Howler Technical (100% *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009), was not an eye irritant following a 24-hour ocular exposure to rabbits. One-tenth of a milliliter of Howler Technical was instilled into the right eyes of three healthy rabbits (MRID No. 495680-06). The left eyes remained untreated and served as controls. Ocular irritation was evaluated using the Draize scoring method. No ocular irritation was observed in any treated eye during the study, and the test substance was classified as non-irritating to the eye (Toxicity Category IV).

6. Primary Dermal Irritation (OCSPP 870.2500): The TGAI, Howler™ Technical (100% *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009), was not a dermal irritant following a 4-hour dermal exposure to rabbits. Five-tenths of a milliliter of Howler Technical was applied to the skin of three healthy rabbits and covered for four hours with a gauze pad and semi-occlusive tape (MRID No. 495680-07). Following exposure, dermal irritation was evaluated using the Draize scoring method. No dermal irritation was observed in any rabbit during the study, and the test substance was classified as non-irritating to the skin (Toxicity Category IV).

7. Hypersensitivity Incidents (OCSPP 885.3400): The registrant has noted that no incidents of hypersensitivity or any other adverse effects have occurred through the research, development or testing of the active ingredient and its related end-use product. Should any incidents occur, they will be reported per FIFRA Section 6(a)(2) (MRID No. 495680-16).

Literature searches have demonstrated that there are no reports of ecological or human health hazards caused by *Pseudomonas chlororaphis* strains. It does not produce recognized toxins, enzymes, or virulence factors normally associated with mammalian invasiveness or toxicity. *Pseudomonas chlororaphis* is an entomopathogenic fungus and a search of the literature demonstrates it is not reported to be pathogenic to humans. A search of the National Library of Medicine, PubMed, using the terms "*Pseudomonas chlororaphis*" AND "mammal" AND "pathogenicity" resulted in "No items found" (MRID No. 495680-16).

The results of toxicity testing show there is no risk to human health from the active ingredient. *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009 is not toxic, pathogenic, infective or irritating to mammals.

D. Aggregate Exposure

1. Dietary exposure.

i. *Food.* Dietary exposure from use of *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009, as proposed, is minimal. The intended use of *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009 is as a biological fungicide to growing plants in greenhouses, agricultural fields and home gardens for the purposes of disease control.

The results of toxicity testing indicate there is no risk to human health or the environment from *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009. There are no reports of ecological or human health hazards caused by this strain of *Pseudomonas chlororaphis*. It does not produce recognized toxins, enzymes, or virulence factors normally associated with mammalian invasiveness or toxicity. The absence of acute toxicity or pathogenicity in laboratory animals demonstrates the benign nature of this strain.

ii. *Drinking water.* Similarly, exposure to humans from residues of *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009 in consumed drinking water would be unlikely. Potential exposure to surface water would be negligible and exposure to drinking water (well or ground water) would be impossible to measure. *Pseudomonas chlororaphis* is a common bacterium found in soils (MRID No. 495680-16).

The intended use of *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009 is to growing plants in greenhouses, agricultural fields and home gardens for the purposes of disease control. The risk of the microorganism passing through the soil to ground water is minimal to unlikely. Additionally the fungus would not tolerate the conditions water is subjected to in a drinking water facility (including: chlorination, pH adjustments, high temperatures and/or anaerobic conditions).

The results of toxicity testing indicate there is no risk to human health or the environment from *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009. There are no reports of ecological or human health hazards caused by this microorganism. It does not produce recognized toxins, enzymes, or virulence factors normally associated with mammalian invasiveness or toxicity. The absence of acute toxicity or pathogenicity in laboratory animals demonstrates the benign nature of this strain.

2. Non-dietary exposure. The intended use of *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009 is to growing plants in greenhouses, agricultural fields and home gardens for the purposes of disease control. Personal Protective Equipment (PPE) mitigates the potential for exposure to applicators and handlers of the proposed products, when used in agricultural settings. *Pseudomonas chlororaphis* is a common bacterium found in soils (MRID No. 495680-16).

The results of toxicity testing indicate there is no risk to human health or the

environment from *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009. There are no reports of ecological or human health hazards caused by this microorganism. It does not produce recognized toxins, enzymes, or virulence factors normally associated with mammalian invasiveness or toxicity. The absence of acute toxicity or pathogenicity in laboratory animals demonstrates the benign nature of this strain. Non-dietary exposures would not be expected to pose any quantifiable risk due to a lack of residues of toxicological concern.

E. Cumulative Effects

It is not expected that, when used as proposed, *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009 would result in residues that are of toxicological concern. The intended use of *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009 is to growing plants in greenhouses, agricultural fields and home gardens for the purposes of disease control. The results of toxicity testing indicate there is no risk to human health or the environment from *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009. There are no reports of ecological or human health hazards caused by this microorganism. It does not produce recognized toxins, enzymes, or virulence factors normally associated with mammalian invasiveness or toxicity. The absence of acute toxicity or pathogenicity in laboratory animals demonstrates the benign nature of this strain.

F. Safety Determination

1. *U.S. population.* Acute toxicity studies have shown that *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009 is not toxic, pathogenic, infective or irritating to mammals. The intended use of *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009 is to growing plants in greenhouses, agricultural fields and home gardens for the purposes of disease control. The results of toxicity testing indicate there is no risk to human health or the environment from *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009. There are no reports of ecological or human health hazards caused by this microorganism. It does not produce recognized toxins, enzymes, or virulence factors normally associated with mammalian invasiveness or toxicity. The absence of acute toxicity or pathogenicity in laboratory animals demonstrates the benign nature of this strain. There is a reasonable certainty of no harm to the general US population from exposure to this active ingredient.

2. *Infants and children.* As mentioned above, it is not expected that, when used as proposed, *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009 would result in residues that are of toxicological concern. There is a reasonable certainty of no harm for infants and children from exposure to *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009 from the proposed uses.

G. Effects on the Immune and Endocrine Systems

To date there is no evidence to suggest that *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009 functions in a manner similar to any known hormone, or that it acts as an endocrine disrupter.

H. Existing Tolerances

There is no US EPA tolerance or tolerance exemption for *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009.

I. International Tolerances

A Codex Alimentarium Commission Maximum Residue Level (MRL) is not established for *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009.

Petition for an exemption from the requirement of a tolerance for residues of products containing the active ingredient "*Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009" in and on all food commodities

Submitted by:

AFS009 Plant Protection, Inc. (EPA Co. No. 91197)
104 T.W. Alexander Drive, Building 18
Research Triangle Park, NC 27709

SECTION A Products and Proposed Use

Product Name: **Howler™ Technical (100% ai; TGAI) – EPA File Symbol 91197-R**
Howler™ (50% ai; EP) – EPA File Symbol 91197-G

Proposed Use Practice: Howler™ Technical is a 100% ai Technical Grade Active Ingredient (TGAI) of *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009 and is proposed for manufacturing use only, for further formulation into registered end-use products.

Howler™ is a 50% ai is formulated end-use product for use on growing plants and crops to control plant diseases including *Rhizoctonia, Pythium, Fusarium, Phytophthora* and *Botrytis*. Howler™ may be mixed with water and applied as a foliar spray, soil drench, in furrow spray, transplant spray or dip, cuttings or bare root dip, hydroponic or chemigation application in greenhouse, agricultural field, turf and ornamental and home and garden use sites.

SECTION B Product identity/chemistry

Active Ingredient: *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009 (CAS No. Not applicable).

Pseudomonas chlororaphis is a common bacterium identified primarily in the soil. *Pseudomonas chlororaphis* subsp. *aurantiaca* is a Gram-negative, rod-shaped bacteria with one or more flagella for motility. Information regarding the name, identity and composition has been submitted to EPA and can be found in MRID No. 495680-01.

Mode of Action: Like other *Pseudomonas chlororaphis* strains *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009 is a plant-colonizing bacteria which controls fungal diseases by several modes of action, including competition and production of a variety of metabolites which are inhibitory to the fungi. (MRID No. 495680-01).

Magnitude of residues and method to determine: An analytical method for residues is not applicable. It is expected that, when used as proposed, *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009, would not result in residues that are of toxicological concern.

SECTION C Toxicological Profile

Studies to evaluate the safety to mammals were conducted on the technical grade active ingredient (TGAI) and are summarized as follows:

1. Acute Oral Toxicity/Pathogenicity Study in Rats (OCSPP 885.3050): Howler™ Technical (100% *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009) was not toxic or pathogenic in rats following acute oral exposure to a concentrate of 3.73×10^9 (MRID No. 495680-02). The MPCA test substance and the inactivated test substance were administered to rats by gavage in single high doses. The animals were observed frequently on the day of dosing (Day 0) for mortality and clinical signs of toxicity, and once daily thereafter for 21 days. An untreated control group was conducted concurrently. Tissue samples from treated rats were enumerated on days 0, 3, 7, 14, and 21. The test organism was not observed in plated blood, brain or liver. The urine from treated rats was completely clear of MPCA growth by 72 hours. The test organism cleared completely from the treated lungs, spleen, and kidney by Day 14. The mesenteric lymph nodes from treated rats did not achieve complete clearance, but declined to very low levels of growth found only in a single animal by Day 21. There were no signs of pharmacologic and/or toxicologic effects observed in any animal during the study, and no mortality occurred. The gross necropsy conducted at termination of the study revealed no internal abnormalities. The test substance, Howler™ Technical, was determined to be non-toxic to rats and demonstrate a pattern of clearance when administered by oral gavage in a single dose of 3.73×10^9 CFU/rat.

2. Acute Oral Toxicity (OCSPP 870.1100): The TGAI, Howler™ Technical (100% *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009), was not toxic following acute exposure by the oral route. An acute oral toxicity study was conducted on rats using the up-and-down procedure to determine the potential for Howler™ Technical to produce toxicity from a single oral dose (MRID No. 495680-03). An initial dose of 5,000 mg per kg body weight of the test substance was administered to a single female rat by gavage. This first rat survived and so two additional rats received a gavage dose of 5,000 mg/kg bw of the test material. All three animals survived, so no additional animals were tested. The rats were observed for mortality, clinical signs of toxicity and behavioral changes daily for 14 days. Body weights were recorded prior to exposure and again on Days 7 and 14. All animals survived test substance administration, gained body weight, and appeared active and healthy during the study. Necropsies were performed on all animals at terminal sacrifice. Under the study conditions, the acute oral LD50 of Howler™ Technical was greater than 5,000 mg/kg body weight in female rats (Toxicity Category IV).

3. Acute Dermal Toxicity (OCSPP 870.1200): The TGAI, Howler™ Technical (100% *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009) was not toxic following acute exposure by the dermal route. An acute dermal toxicity study was conducted on rats to determine the potential for Howler Technical to produce toxicity from a single topical application (MRID No. 495680-04). Five thousand milligrams (mg) of the test substance per kilogram (kg) of body weight was applied to the skin of 5 male and 5 female rats for 24 hours. The rats were observed for mortality, clinical signs of toxicity and behavioral changes daily for 14 days. Body weights were recorded prior to exposure and again on

Days 7 and 14. Necropsies were performed on all animals at terminal sacrifice. Under the study conditions, the single dose acute dermal LD50 of Howler™ Technical was greater than 5,000 mg/kg body weight in male and female rats (Toxicity Category IV).

4. Acute Inhalation Toxicity Study in Rats (OCSPP 870.1300): An acute inhalation study demonstrates that the microbial pest control agent (MPCA), Howler™ Technical is not toxic by the inhalation route (MRID No. 495680-05). The TGAI, Howler™ Technical was not toxic to rats following an acute inhalation exposure. An acute inhalation toxicity study was conducted on rats to determine the potential for Howler™ Technical to produce toxicity from a single 4-hour inhalation exposure. Ten healthy rats (5/sex) were exposed to the test atmosphere in a nose-only chamber for 4 hours. Chamber concentration and particle size distributions of the test atmosphere were determined periodically during the exposure period. The gravimetric chamber concentration was 5.04 mg/L and the average mass median aerodynamic diameter was estimated to be 2.39 µm. The animals were observed for mortality, clinical signs of toxicity, and behavioral changes daily for 14 days following exposure. Body weights were recorded prior to exposure and again on Days 1, 3, 7, and 14. Necropsies were performed on all animals at terminal sacrifice. Under the study conditions, the single dose acute inhalation LC50 of Howler Technical for a 4-hour exposure was greater than 5.05 mg/L (Toxicity Category IV).

5. Primary Eye Irritation (OCSPP 870.2400): The TGAI, Howler Technical (100% *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009), was not an eye irritant following a 24-hour ocular exposure to rabbits. One-tenth of a milliliter of Howler Technical was instilled into the right eyes of three healthy rabbits (MRID No. 495680-06). The left eyes remained untreated and served as controls. Ocular irritation was evaluated using the Draize scoring method. No ocular irritation was observed in any treated eye during the study, and the test substance was classified as non-irritating to the eye (Toxicity Category IV).

6. Primary Dermal Irritation (OCSPP 870.2500): The TGAI, Howler™ Technical (100% *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009), was not a dermal irritant following a 4-hour dermal exposure to rabbits. Five-tenths of a milliliter of Howler Technical was applied to the skin of three healthy rabbits and covered for four hours with a gauze pad and semi-occlusive tape (MRID No. 495680-07). Following exposure, dermal irritation was evaluated using the Draize scoring method. No dermal irritation was observed in any rabbit during the study, and the test substance was classified as non-irritating to the skin (Toxicity Category IV).

7. Hypersensitivity Incidents (OCSPP 885.3400): The registrant has noted that no incidents of hypersensitivity or any other adverse effects have occurred through the research, development or testing of the active ingredient and its related end-use product. Should any incidents occur, they will be reported per FIFRA Section 6(a)(2) (MRID No. 495680-16).

Literature searches have demonstrated that there are no reports of ecological or human health hazards caused by *Pseudomonas chlororaphis* strains. It does not produce recognized toxins, enzymes, or virulence factors normally associated with mammalian invasiveness or toxicity. *Pseudomonas chlororaphis* is an entomopathogenic fungus and a search of the literature

demonstrates it is not reported to be pathogenic to humans. A search of the National Library of Medicine, PubMed, using the terms "*Pseudomonas chlororaphis*" AND "mammal" AND "pathogenicity" resulted in "No items found" (MRID No. 495680-16).

The results of toxicity testing show there is no risk to human health from the active ingredient. *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009 is not toxic, pathogenic, infective or irritating to mammals.

SECTION D Aggregate Exposure

1) Dietary Exposure:

Dietary exposure from use of *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009, as proposed, is minimal. The intended use of *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009 is as a biological fungicide to growing plants in greenhouses, agricultural fields and home gardens for the purposes of disease control.

The results of toxicity testing indicate there is no risk to human health or the environment from *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009. There are no reports of ecological or human health hazards caused by this strain of *Pseudomonas chlororaphis*. It does not produce recognized toxins, enzymes, or virulence factors normally associated with mammalian invasiveness or toxicity. The absence of acute toxicity or pathogenicity in laboratory animals demonstrates the benign nature of this strain.

2) Drinking Water Exposure:

Similarly, exposure to humans from residues of *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009 in consumed drinking water would be unlikely. Potential exposure to surface water would be negligible and exposure to drinking water (well or ground water) would be impossible to measure. *Pseudomonas chlororaphis* is a common bacterium found in soils (MRID No. 495680-16).

The intended use of *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009 is to growing plants in greenhouses, agricultural fields and home gardens for the purposes of disease control. The risk of the microorganism passing through the soil to ground water is minimal to unlikely. Additionally the fungus would not tolerate the conditions water is subjected to in a drinking water facility (including: chlorination, pH adjustments, high temperatures and/or anaerobic conditions).

The results of toxicity testing indicate there is no risk to human health or the environment from *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009. There are no reports of ecological or human health hazards caused by this microorganism. It does not produce recognized toxins, enzymes, or virulence factors normally associated with mammalian invasiveness or toxicity. The absence of acute toxicity or pathogenicity in laboratory animals demonstrates the benign nature of this strain.

3) Non-Dietary Exposure:

The intended use of *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009 is to growing plants in greenhouses, agricultural fields and home gardens for the purposes of disease control. Personal Protective Equipment (PPE) mitigates the potential for exposure to applicators and handlers of the proposed products, when used in agricultural settings. *Pseudomonas chlororaphis* is a common bacterium found in soils (MRID No. 495680-16).

The results of toxicity testing indicate there is no risk to human health or the environment from *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009. There are no reports of ecological or human health hazards caused by this microorganism. It does not produce recognized toxins, enzymes, or virulence factors normally associated with mammalian invasiveness or toxicity. The absence of acute toxicity or pathogenicity in laboratory animals demonstrates the benign nature of this strain. Non-dietary exposures would not be expected to pose any quantifiable risk due to a lack of residues of toxicological concern.

SECTION E Cumulative Effects

It is not expected that, when used as proposed, *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009 would result in residues that are of toxicological concern. The intended use of *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009 is to growing plants in greenhouses, agricultural fields and home gardens for the purposes of disease control. The results of toxicity testing indicate there is no risk to human health or the environment from *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009. There are no reports of ecological or human health hazards caused by this microorganism. It does not produce recognized toxins, enzymes, or virulence factors normally associated with mammalian invasiveness or toxicity. The absence of acute toxicity or pathogenicity in laboratory animals demonstrates the benign nature of this strain.

SECTION F Safety Determination

1) General US Population:

Acute toxicity studies have shown that *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009 is not toxic, pathogenic, infective or irritating to mammals. The intended use of *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009 is to growing plants in greenhouses, agricultural fields and home gardens for the purposes of disease control. The results of toxicity testing indicate there is no risk to human health or the environment from *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009. There are no reports of ecological or human health hazards caused by this microorganism. It does not produce recognized toxins, enzymes, or virulence factors normally associated with mammalian invasiveness or toxicity. The absence of acute toxicity or pathogenicity in laboratory animals demonstrates the benign nature of this strain. There is a reasonable certainty of no harm to the general US population from exposure to this active ingredient.

2) Infants and Children:

As mentioned above, it is not expected that, when used as proposed, *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009 would result in residues that are of toxicological concern. There is a reasonable certainty of no harm for infants and children from exposure to *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009 from the proposed uses.

SECTION G – Effects on Immune and Endocrine Systems

To date there is no evidence to suggest that *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009 functions in a manner similar to any known hormone, or that it acts as an endocrine disrupter.

SECTION H – Existing Tolerances

There is no US EPA tolerance or tolerance exemption for *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009.

SECTION I – International Tolerances

A Codex Alimentarium Commission Maximum Residue Level (MRL) is not established for *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009.

DOES THIS FORM CONTAIN CONFIDENTIAL BUSINESS INFORMATION? Yes _____ No X

DATE of PRESUBMISSION MEETING:
October 2, 2014. 1 PM – 2 PM Eastern time

OPTIONAL FORM 99 (7-90)
FAX TRANSMITTAL # of pages ▸ 9
To Amy Roberts | From Ann Sibold
Dept./Agency | Phone # 703 305-6502
Fax # 530 757-1299 | Fax #
NSN 7540-01-317-7368 5099-101 GENERAL SERVICES ADMINISTRATION

APPLICANT:
Kelly S. Smith
AgBiome, Inc.
104 T.W. Alexander Dr., Bldg 18
Research Triangle Park, NC 27709
352-284-7252; ksmith@agbiome.com

AGENT (If applicable): Amy Plato Roberts | Senior Regulatory Consultant
Technology Sciences Group Inc. (TSG)
PO Box 990 | Hailey, ID 83333 USA
Tel: 202.684.2784 | Fax: 530.757.1299 | Email: aroberts@TSGUSA.com

PARTICIPANTS (Names, Titles, and Affiliations, with any attorneys identified):
Dan Tomso, AgBiome
Amy Plato Roberts, Senior Regulatory Consultant, TSG
Kelly S. Smith, AgBiome
Chris Burnside, TSG
Beth Mileson, TSG
Mike Mendelsohn, MPB
John Kough, Senior Scientist, MPB
Shannon Borges, Team Leader, MPB
Ann Sibold, MPB

PURPOSE OF MEETING (e.g., Discuss new registration, new use, first food use, amendment, EUP, etc.):
B590, new active ingredient registration, food use with a tolerance exemption. Will include a TGAI and an EP.
JOINT REVIEW with PMRA, EU, OECD, Other (specify): Yes____ No __X___

TYPE OF APPLICATION (EUP, Sec. 3 REGISTRATION:
B590, new active ingredient registration, food use with a tolerance exemption. Will include a TGAI and an EP.

PRIA FEES: Fees for a B590. Small business fee waiver will be requested.
$30,390 17 months review time.

ACTIVE INGREDIENT (AI) (If more than one, specify the following for each):

Name: *Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009. Deposit is pending with the Agricultural Research Service Culture Collection. This is a new subspecies. Submit information on reclassification & how it compares to previously registered strain of chloroaphis.

Country of Origin: USA

Currently registered, previously registered, or new AI:
New active ingredient.

Mode of action toward targeted pest(s):
Plant tissue colonization and competition with plant pathogens.

USDA Permits Required (specify): Not required – is a US indigenous strain.

Regulatory History (e.g., previously registered; EUP, registered in another country):
New active ingredient, never before registered.

Applying for USDA National Organic Program (NOP) certification?
Yes

PRODUCT INFORMATION

Product Name(s)	Product type (EP, MP)	Active Ingredient(s)	Proposed Use Pattern(s)	Proposed Use Site(s)	Proposed Pest(s)
Howler™ Technical	TGAI/MP	*Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009	For manufacturing use only.		
Howler™ EP	EP	*Pseudomonas chlororaphis* subsp. *aurantiaca* strain AFS009	Terrestrial food use, greenhouse food use, home & garden	Greenhouse ornamentals and food crops, turf, soybean, corn, wheat	Rhizoctonia, Fusarium, Botrytis, Pythium,

MEETING NOTES for this section. (This will be filled in during the meeting by the note taker)
If Asian soybean rust is added to label, efficacy data may be needed. AgBiome should discuss with APHIS.

Sublabels may include home & garden.

Cotton may be included.

DATA REQUIREMENTS[1]

(Does not include Tier II and III data or Residue Data)

Guideline Number	Title	Specify How Data Requirement Will Be Satisfied				MEETING NOTES (This will be filled in during the meeting by the note taker)
		Guideline Study - Test Material (TGAI, MP, EP)	Cited Data/Source - Test Material	Are Cited Data Compensable?	Request to Waive the Data Requirement Based Upon:	
Product Chemistry and Composition						
885.1100	Product Identity	TGAI/MP and EP				Info will be submitted.
885.1200	Manufacturing process	TGAI/MP and EP				Info will be submitted. Aseptic, submerged fermentation. Contractor will manufacture.
885.1250	Deposition of a sample in a nationally recognized culture collection	TGAI				Info will be submitted. Deposited at NRRL.
885.1300	Discussion of formation of unintentional ingredients	TGAI/MP and EP				Info will be submitted. Consult OECD guidance. Consider nature of fermentation. Listeria may be a consideration. Discuss nature of mode of action. Is it an excreted compound or competitive exclusion.
Analysis and Certified Limits						
885.1400	Analysis of samples	TGAI/MP and EP				Info will be submitted.
885.1500	Certification of limits	TGAI/MP and EP				Info will be submitted.
Physical and Chemical Characteristics						
830.6302	Color	TGAI/MP				Info will be submitted.
830.6303	Physical state	TGAI/MP				Info will be submitted.
830.6304	Odor	TGAI/MP				Info will be submitted.
830.6313	Stability to normal and elevated temperatures, metals and metal ions	TGAI/MP				Info will be submitted.
830.6317	Storage stability	TGAI/MP and EP				Info will be submitted. Gram negative organism. Will be a wettable powder.
830.6319	Miscibility					Not applicable per 40 CFR Part 158 test note.
830.6320	Corrosion Characteristics	TGAI/MP and EP				Info will be submitted.
830.7000	pH	TGAI/MP and EP				Info will be submitted.
830.7100	Viscosity					Not applicable per 40 CFR Part 158 test note.
830.7300	Density/relative density/bulk density	TGAI/MP				Info will be submitted.

Guideline Number	Title	Specify How Data Requirement Will Be Satisfied				MEETING NOTES (This will be filled in during the meeting by the note taker)
		Guideline Study - Test . Material (TGAI, MP, EP)	Cited Data/Source - Test Material	Are Cited Data Compensable?	Request to Waive the Data Requirement Based Upon:	
	(specific gravity)	and EP				

MEETING NOTES for this section, (This will be filled in during the meeting by the note taker)

Recent reclassification supporting information should be submitted.

Toxicology & Pathogenicity						
Guideline Number[2]	Title	Specify How Data Requirement Will Be Satisfied				MEETING NOTES (This will be filled in during the meeting by the note taker)
		Guideline Study - Test Material (TGAI, MP, EP)	Cited Data/Source - Test Material	Are Cited Data Compensable?	Request to Waive the Data Requirement Based Upon:	
Tier I						
885.3050	Acute oral toxicity/pathogenicity	TGAI				A study will be submitted. Pattern of Clearance must be established. Necropsy findings, moving across gut membrane? Clearance pattern established but not in all organisms. This may be an issue if you want to waive other studies.
885.3150	Acute pulmonary toxicity/pathogenicity	TGAI			Yes	Rationale based on oral tox/path and published lit. We suggest they do a study that establishes a pattern of clearance. Recommend that you do an IV-Path study to establish pattern of clearance with maximum hazard dose. It is hard to show clearance with IP. If this is a new strain, how do you make link to published literature? It doesn't grow at human temperature. May try as part of a waiver rationale.
885.3200	Acute injection toxicity/pathogenicity/(intravenous) Acute injection toxicity/pathogenicity/(intraperitoneal)	TGAI			Yes	Rationale based on oral tox/path and published lit.
885.3400	Hypersensitivity incidents					None to date. Any incidents must be reported.
885.3500	Cell culture					Not applicable.
870.1100	Acute oral toxicity	TGAI/MP and EP			Yes for EP.	A study will be submitted for the TGAI/MP. Rationale

						for EP based on TGAI data and info on inerts.
870.1200	Acute dermal toxicity	TGAI/MP and EP			Yes for EP.	A study will be submitted for the TGAI/MP. Rationale for EP based on TGAI data and info on inerts.
870.1300	Acute inhalation toxicity	TGAI/MP and EP			Yes for EP.	A study will be submitted for the TGAI/MP. Rationale for EP based on TGAI data and info on inerts.
870.2400	Acute eye irritation	TGAI/MP and EP			Yes for EP.	A study will be submitted for the TGAI/MP. Rationale for EP based on TGAI data and info on inerts.
870.2500	Primary dermal irritation	TGAI/MP and EP			Yes for EP.	A study will be submitted for the TGAI/MP. Rationale for EP based on TGAI data and info on inerts.

MEETING NOTES for this section. (This will be filled in during the meeting by the note taker)

Recommend doing some acute tox studies using formulated product. Fresh cell suspension may not be sufficient. Inerts may affect cell toxicity. Endotoxins may come from gram negative ai.

Nontarget Organism Testing						
Guideline Number[2]	Title	Specify How Data Requirement Will Be Satisfied				MEETING NOTES (This will be filled in during the meeting by the note taker)
		Guideline Study - Test Material (TGAI, MP, EP)	Cited Data/Source - Test Material	Are Cited Data Compensable?	Request to Waive the Data Requirement Based Upon:	
Tier 1						
885.4050	Avian oral toxicity	TGAI				A study will be submitted.
885.4100	Avian inhalation toxicity/pathogenicity	TGAI			Yes	Rationale based on avian oral data, published lit, lack of exposure from application methods. We suggest they not use lack of exposure as part of the rationale. Any issues with toxins must be addressed in rationale. Any literature search should include information on how search was conducted.
885.4150	Wild mammal toxicity/pathogenicity	TGAI			Yes	Rationale based on other tox data, published lit and lack of exposure from application methods. We suggest they not use lack of exposure as part of the rationale. Any issues with toxins must be addressed in rationale. Any literature search should include information on how search was conducted.
885.4200	Freshwater fish toxicity/ pathogenicity	TGAI				A study will be submitted.
885.4240	Freshwater invertebrate toxicity/pathogenicity	TGAI				A study will be submitted.
885.4280	Estuarine/Marine fish testing Estuarine and marine invertebrate testing	TGAI			Yes	Rationale based on aquatic tox data, published lit, lack of exposure from application methods. The rationale for lack of exposure should be scientifically sound. We generally don't accept freshwater aquatic tox data as part of the rationale for marine, estuarine testing.
885.4300	Nontarget plant testing	TGAI			Yes	Rationale based on lack of phytotox in efficacy data and published lit. You can submit efficacy data

						as part of the rationale. You must address pathogenicity.
885.4340	Nontarget insect testing	TGAI				A study will be submitted. We recommend three species for testing.
885.4380	Honey bee testing	TGAI				A study will be submitted.

[1] Specific data requirements are dependent upon the type of product and intended uses. Note that all required data must be submitted for *each* product. Data requirements may be satisfied by conducting guideline studies, citation of existing MRID study, citation of a public literature study, a study generated at government expense, or a request to be waived from satisfying a data requirement supported by a scientifically based rationale explaining why the waiver applies to the product (40 CFR 152.91 & 152.94; 158.45).

[2]Guideline Numbers-Orange shaded boxes: For testing conducted by a laboratory contractor: Test substances (including sterile production filtrate, pesticidal active ingredient), other negative/positive controls used in the study and provided by the Sponsor must have a Certificate of Authenticity included in the specific study report. The Certificate must be signed and dated by the Sponsor (with the signed name typed below the signature line), and must include: purity, Lot number, potency (if applicable, and indicate how the potency was determined; if an SOP is available the SOP should be included in the Product Characterization/Analysis portion of the submission, OCSPP Guideline No. 885.1400), viability of the test material (if applicable), volume or weight of the test material provided to the Testing Facility, the expiration date of the test item, storage conditions, form (liquid, solid, powder, granule).

For a sterile production filtrate, provide the time of "harvest"(e.g., 24 hours after initial start of fermentation, "logarithmic phase" or "lag phase", how the filtrate was prepared, size of filter, volume and diluent (if any). Indicate the viability (cfu/ml) of the "harvested" batch. The sterile production filtrate should be prepared from the same Lot/Batch as the Test Substance, using aseptic technique and sterilized filter apparatus, and free of insoluble material and not cloudy or turbid, describe the color and contents of the filtrate (i.e., culture/fermentation medium), especially if it contains spent "fermentation media".

MPB recommends the registrant provide pre-populated Data Evaluation Report (DERs). The DER templates are available on the EPA website at:
http://www.epa.gov/pesticides/biopesticides/regtools/oecd-der-template.html

MEETING NOTES for this section. (This will be filled in during the meeting by the note taker)

OTHER MEETING NOTES (This will be filled in during the meeting by the note taker)

Efficacy Data

Efficacy data are required for public health pests and termites. See the following website for guidance.
http://www.epa.gov/ocspp/pubs/frs/publications/Test_Guidelines/series810.htm

MEETING NOTES for this section. (This will be filled in during the meeting by the note taker)

The following data may be required as a result of the Tier I test results:

Human Health

Tier II	
885.3550	Acute toxicity
885.3600	Subchronic toxicity/pathogenicity
Tier III	
885.3650	Reproductive fertility effects

870.4200	Carcinogenicity
870.7800	Immunotoxicity
885.3000	Infectivity/pathogenicity analysis

Environmental Fate and Nontarget Effects

Tier II	
885.5200	Terrestrial environmental expression tests
885.5300	Freshwater environmental expression tests
885.5400	Marine or estuarine environmental expression tests
Tier III	
885.4600	Avian chronic pathogenicity and reproduction test
885.4650	Aquatic invertebrate range testing
885.4700	Fish life cycle studies
885.4750	Aquatic ecosystem test
Tier IV	
850.2500 850.1950	Field testing for terrestrial wildlife and Field testing for aquatic organisms
850.2500	Simulated or actual field tests (birds, mammals)
850.1950	Simulated or actual field test (aquatic organisms)
850.2500	Simulated or actual field tests (insect predators, parasites)
850.3040	Simulated or actual field tests (insect pollinators)
850.4300	Simulated or actual field tests (plants)

PRIA FEES:

PRIA Fees PRIA fee schedule is available at: http://www.epa.gov/pesticides/fees/tool/category-table.html#bppd	
PRIA Code	B590
PRIA Fee	$30,390
PRIA timeline	17 months

MEETING NOTES for this section. (This will be filled in during the meeting by the note taker.)

Other Considerations:

MPB recommends the registrant provide pre-populated Data Evaluation Report (DERs). The DER templates are available on the EPA website at: http://www.epa.gov/pesticides/biopesticides/regtools/oecd-der-template.html

Please note that these DER templates also include guidance for developing scientific rationale in lieu of conducting the specific study for each data requirement.

OPP recommends electronic submission of application(s): Guidance is provided at: http://www2.epa.gov/pesticide-registration/electronic-submissions-pesticide-applications